PB90-146556

REGISTRATION STANDARD FOR PESTICIDE PRODUCTS CONTAINING MCPA AS THE ACTIVE INGREDIENT

(U.S.) Environmental Protection Agency
Washington, DC

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Pesticides and
Toxic Substances
(H-7501C)

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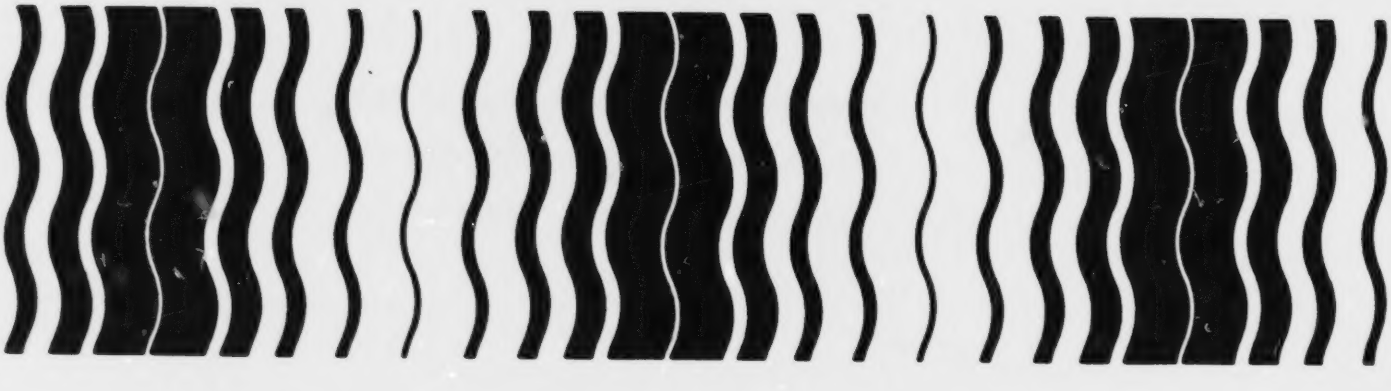
EPA

Registration Standard For Pesticide Products Containing MCPA As The Active Ingredient



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GUIDANCE

FOR THE

REREGISTRATION OF PESTICIDE PRODUCTS

CONTAINING

	OPP CHEMICAL CODE
MCPA (2-Methyl-4-chlorophenoxyacetic Acid)	030501
MCPA, Sodium Salt	030502
MCPA, Dimethyanolamine Salt	030511
MCPA, Dimethylamine Salt	030516
MCPA, Butoxyethyl Ester	030553
MCPA, Butyl Ester	030556
MCPA, Isobutyl Ester	030562
MCPA, Isooctyl Ester	030563
MCPA, Isopropyl Ester	030566

AS THE ACTIVE INGREDIENT

CASE NUMBER 0017

September 1989

ENVIRONMENTAL PROTECTION AGENCY

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This document contains information regarding the registration of pesticide products containing the subject active ingredient. The document includes how to register under a registration standard, regulatory position and rationale, and summaries of date requirements and data gaps. Also included is a bibliography containing citations of all studies reviewed by EPA in arriving at the positions and conclusions contained in the standard.

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GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. Also known as the Reference Dose or RfD.
a.i.	active ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CSF	Confidential Statement of Formula
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End Use Product
EPA	U.S. Environmental Protection Agency
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
LC50	Median lethal concentration - a statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water or feed, e.g., mg/l or ppm.
LD50	Median lethal dose - a statistically derived single dose than can be expected to cause death in 50% of the test animals, when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LEL	Lowest Effect Level
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted to the Agency.
MP	Manufacturing Use Product
NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
OPP	Office of Pesticide Programs

PADI	Provisional Acceptable Daily Intake
ppm	parts per million
RfD	Reference Dose
TMRC	Theoretical Maximal Residue Contribution

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I. INTRODUCTION

This document is a revised Registration Standard for the subject chemical. In its original Standard, issued on March 1982 the Agency summarized the available data supporting the registration of the pesticide and its assessment of those data to determine whether the pesticide met the "no unreasonable adverse effects" standard of FIFRA. The Agency concluded that additional data were necessary to fully evaluate the pesticide, and, as part of the issuance of the Standard, required that registrants supply those data. The Standard also set out labeling requirements that the Agency believed were necessary to ensure that products containing the pesticide were adequate to protect public health and the environment while the data were under development.

The Agency has since reviewed the additional data and has updated and revised its scientific and regulatory conclusions concerning the pesticide in light of expanded data requirements promulgated in 1984 as 40 CFR Part 158. The Registration Standard contains the Agency's updated scientific assessment[1] of this pesticide and its currently registered uses. As part of its review, the Agency has reassessed the tolerances for the pesticide and determined whether they are adequate. The tolerance reassessment is included in this Registration Standard.

Based on the new data, the Agency has also reviewed the labeling requirements for the pesticide and is requiring label revisions.

This revised Registration Standard supersedes the original Registration Standard in its entirety.

This document contains the following sections:

° Section II describes the particular pesticide(s) covered by this Registration Standard, and gives a brief profile of its usage and composition. Regulatory history may be provided as well.

° Section III sets out the Agency's scientific assessment of the health risks and environmental characteristics and effects of the chemical, updated based on data submitted to the Agency under the original Registration Standard.

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[1] The scientific reviews and Compendium of Acceptable Uses may be obtained from the OPP Public Docket. Write to OPP Public Docket, Field Operations Division (H7506c), Office of Pesticide Programs, EPA, Washington, D,C. 20460.

° Section IV explains the regulatory decisions and conclusions arising from the Agency's assessment, and the rationales for its decisions. Section IV also describes the labeling statements required for products containing the chemical. These are divided into statements for manufacturing use products and statements for end use products.

° Sections V, VI, VII, VIII and IX describe what products are subject to the data and labeling requirements set out in this Registration Standard, and what is required of registrants to comply with the requirements.

° Appendix I contains a series of tables setting out data requirements for the chemical. The tables identify which requirements have been satisfied, as well as those for which gaps remain. A Guide to Tables introduces the tables.

° Appendix II is a series of labeling information sheets, setting out general labeling information that must be placed on labeling.

° Appendix III is a bibliography of the data evaluated by the Agency in its assessment. A Guide to Bibliography explains how to read and use the Bibliography.

Registrants are reminded that FIFRA sec. 6(a)(2) requires them to submit factual information concerning possible unreasonable adverse effects of a pesticide at any time that they become aware of such information. Registrants must notify the Agency of any information, including interim or preliminary results of studies, if that information suggests possible adverse effects on man or the environment. This requirement is independent of the specific time requirements imposed by EPA for submittal of completed studies called in by the Agency and continues as long as the products are registered under FIFRA.

II. CHEMICALS COVERED BY THIS STANDARD

A. Description of the Chemicals

This Standard covers 2-methyl-4-chlorophenoxyacetic acid (MCPA), and its sodium salt, esters and organic amines.

Most often, the acid is formulated into the end-use product (EP). However, an EP may be in the form of a sodium salt, an ester, or organic amine. With these formulations, the esters or amines may greatly influence the physical characteristics, biological activity and environmental fate of the chemical. Therefore, the data requirements in this Standard, address not only the acid and it inorganic salts but also the amine salts and esters.

Trade Names: Acme MCPA Amine 4, Agritox, Agro one, Bordermaster, BH MCPA, Chiptox, Ded-Weed, Empal, Kilsem, Mephanac, Methoxone, Phomene, Rhonox, and Weedar.

Physical Characteristics: The following codes are depicted below for the acid, salts, and esters of MCPA presented in order of the Shaughnessy Numbers. The abbreviations used are: EF - Empirical Formula; MW - Molecular Weight; CAS - Chemical Abstracts Service Registry Number; SN - Shaughnessy Number.

MCPA Acid

EF: $C_9H_9ClO_3$
MW: 200.6
CAS: 94-74-6
SN: 030501

Sodium Salt

EF: $C_9H_8ClNaO_3$
MW: 222.6
SN: 030502

Diethanolamine Salt

EF: $C_{11}H_{16}ClNO_4$
MW: 261.5
SN: 030511

Dimethylamine Salt

EF: $C_{15}H_{16}ClO_3$
MW: 245.7
SN: 030516

Butoxyethyl Ester

EF: $C_{15}H_{21}ClO_4$
MW: 300.8
SN: 030553

Butyl Ester

EF: $C_{13}H_{17}ClO_3$
MW: 256.5
SN: 030556

Isobutyl Ester

EF: $C_{13}H_{17}ClO_3$
MW: 256.5
SN: 030562

Isooctyl Ester

EF: $C_{17}H_{25}ClO_3$
MW: 312.8
CAS: 26544-20-7
SN: 030563

Isopropyl Ester

EF: $C_{12}H_{15}ClO_3$
MW: 242.5
SN: 030566

The following are the physical and chemical characteristics of purified MCPA:

Color: White to light brown

Physical State: Can be solid, flakes, crystal powder, or liquid

Odor: None to slight phenolic odor

Melting Point: 114 to 119° C

Boiling Point: 350° F

Specific Gravity: 1.06

Solubility (g/100 g solvent at 20° C):
0.03 water
50.2 ethyl ether
5.5 chloroform
91.8 acetone
3.3 benzene

B. Use Profile

Type of Pesticide: Herbicide; Plant Growth Regulator.

Pests Controlled: Broadleaf weeds; grasses and other monocots; woody plants; aquatic weeds; and nonflowering plants.

Registered Uses: Terrestrial, food and nonfood; aquatic, food; domestic; and forestry.

Predominant Uses: Postemergent weed control in small grains (wheat, oats, barley, rye), rice, home lawns, ornamental turf, and peas. Other registered use sites with lesser usage include flax, grass seed crops, noncrop areas, pasture grasses, rangeland grasses, grain sorghum, alfalfa, clovers, beans and noncrop areas.

Mode of Activity: MCPA is absorbed through both leaves and roots and is readily translocated throughout the plant. MCPA stimulates nucleic acid and protein synthesis affecting the activity of enzymes, respiration and cell division. Broadleaf plants exhibit malformed leaves, stems and roots.

Formulation Types Registered: Granular (MCPA acid and isooctyl ester); Soluble concentrate/liquid (sodium salt, diethanolamine, dimethyl salt, dimethylamine salt); Technical (MCPA acid, Butoxyethyl ester, isooctyl ester); Formulation Intermediate (Butyl ester, isobutyl ester, isopropyl ester, dimethylamine salt, MCPA acid); Ready-To-Use (Dimethylamine salt); and Emulsifiable Concentrate (Butoxyethyl ester, isooctyl ester). There are 117 federally registered products containing MCPA as an active ingredient either by itself or in combination with other pesticides.

Methods of Application: Aerial and ground equipment, knapsack sprayers, pressure and hose-end applicators, and lawn spreaders.

C. History

MCPA was first registered for pesticidal use in the United States in 1973. MCPA has uses similar to 2,4-D. It is apparently the major chemical used in Europe as a postemergent broadleaf herbicide, whereas in the U.S., 2,4-D is the predominant herbicide. The major technical producers of MCPA are: Dow Chemical Company in the U.S. and Kemisk Vaerk Koge in Denmark. The major formulators are Vertak, Rhone-Poulenc, and the Platte Chemical Company.

The Agency issued a Registration Standard on MCPA and its salts and esters in 1982. In that document, the Agency considered MCPA and the sodium salt as one entity for most categories of testing. Registrants of products containing esters and amines of MCPA acid had the option of providing all data on each ester or amine derivative or of citing data showing that a particular amine or ester would be equivalent to MCPA acid under test conditions. Discussions did take place between registrants and EPA on this matter. However, no definitive decisions were made by EPA and this equivalency issue is unresolved. The Agency is now assessing all data available concerning MCPA.

III. AGENCY ASSESSMENT

A. STATUS OF THE DATA BASE

Toxicology. The 1982 MCPA Registration Standard required a full battery of toxicologic testing on MCPA acid, each salt and ester. The Registrants were given the opportunity to submit evidence which substantiated that a particular salt or ester derivative would be toxicologically equivalent to the MCPA acid. The Agency also identified conflicting studies on the teratogenic, fetotoxic, mutagenic, and spermatogenic potential for MCPA.

From data submitted since the issuance of the 1982 standard, the Agency has determined that MCPA does not have fetotoxic and spermatogenic potential. A gene mutation study is still required. (Structural Chromosomal and DNA Damage and Repair studies were negative). Teratogenicity testing is still required (the unacceptable studies showed no evidence of compound related effects). Special neurotoxicity testing is now required because of MCPA's structural similarity to 2,4-D (2,4-D is suspected of causing neuropathy in humans). The issue of the equivalency of the acid, salts, and esters still remains and if it cannot be shown, the Agency is requiring a full battery of toxicology testing on all the derivatives.

Environmental Fate. There is insufficient information to fully assess the environmental fate of MCPA acid and its derivatives. As stated above, registrants were given the opportunity to show that MCPA acid would satisfy the data requirements for the derivatives, but no data has been submitted. On rereview of studies used for the 1982 assessment, the hydrolysis, photolysis, leaching, and aquatic field dissipation studies are now unacceptable and new studies must be submitted.

Ecological Effects. The 1982 standard required a full battery of fish and wildlife testing on MCPA acid and its derivatives. The ecological effects data base is fairly complete for the acid and sodium salt derivative (an avian reproduction, a shrimp LC_{50}, an aquatic organism accumulation, and nontarget plant phytotoxicity studies are required). Extensive data requirements remain for the amine salts and ester derivatives.

Residue Chemistry. Only plant metabolism data were required to support the established tolerances for residues in or on plant or animal commodities in the 1982 document. As a result of the new residue chemistry guidelines and other policy changes since issuance of the first standard, the Agency is now requiring additional data on the identity and quantities of residue on plants and animals. Storage stability data not required in 1982 are now required. Further data on the magnitude and levels of residues in raw agricultural commodities, animal products, and processed food and feed items are required. Data are not adequate to support all of the established tolerances.

B. TOXICOLOGICAL ASSESSMENT

This section discusses acceptable toxicological data available to the Agency for MCPA. From a toxicological standpoint, the acid and sodium salt are considered equivalent. The toxicology of MCPA acid is presented first, with the limited acute data for the esters and amine salts presented separately.

The 1982 MCPA registration standard required a full battery of toxicological testing on MCPA acid, each salt and each ester. Alternatively, registrants could submit evidence which substantiated that a particular salt or ester would be toxicologically equivalent to MCPA acid. The issue of MCPA acid data supporting the data requirements for the various derivatives has not been resolved. The 1982 standard also identified conflicting studies on the teratogenic, fetotoxic, mutagenic, and spermatogenic potential of MCPA. These conflicts prevented the Agency from making a toxicologic assessment of MCPA at that time. Since the issuance of the 1982 standard, toxicology data has been submitted by registrants and reviewed by the Agency to eliminate many of these conflicts. The following is the Agency's toxicological assessment.

Acute Toxicity Data

Acute Oral. Data are available to show that technical grade MCPA acid is of moderate acute toxicity to rats. The acute oral LD_{50} for rats is 1.383 g/kg in male rats and 0.765 g/kg in female rats; Toxicity Category III. No additional acute oral studies are required for MCPA acid.

Acute Dermal. Data are available to show that technical MCPA acid is of low acute dermal toxicity to rabbits. In a 14-day repeated dose dermal toxicity study, no mortality was observed at doses of 2000 or 4000 mg/kg. Therefore, the LD_{50} for MCPA is set at > 4000 mg/kg (male and female rats); Toxicity Category III. No additional acute dermal studies are required for MCPA acid.

Acute Inhalation. Data are available to show that technical MCPA acid is moderately acutely toxic via inhalation to rats. The acute inhalation LC_{50} (4-hour exposure) is > 6.36 mg/L; Toxicity Category III. No additional acute inhalation studies are required for MCPA acid.

Primary Eye Irritation. Technical MCPA acid has been placed in Toxicity Category I for primary eye irritation based on the observation of corneal opacity with irritation of conjunctivae observed in one of 6 rabbits 21 days postinstillation for a soluble concentrate formulation. No additional primary eye irritation studies are required for MCPA acid.

Primary Skin Irritation. No primary skin irritation study is available on technical MCPA acid. A study is required.

Dermal Sensitization. Data are available to show that technical MCPA acid is not a dermal sensitizer in guinea pigs. However, other supplementary testing exhibited some skin erythema or irritation. Additional testing is required.

Acute Delayed Neurotoxicity. No acute delayed neurotoxicity study is available on MCPA. Since MCPA is not an organophosphate, nor is it reported to produce acetyl cholinesterase inhibition, a study is not required.

Subchronic Oral

Sufficient data are available to satisfy the requirements for a subchronic oral study in rodents and nonrodents.

Oral administration of MCPA (technical, purified) to male and female beagles (0, 3, 12, and 48 mg/kg/day) and a repeat study (0, 0.3, 1, and 12 mg/kg/day) for 13 weeks resulted in severe toxicity and mortality at the HDT (48 mg/kg/day). There was evidence of dose-related liver and kidney toxicity (changes in serum enzymes, decreased ability to filter dyes). These effects were found in both sexes at dose levels down to 3 mg/kg/day and were associated with kidney and liver histopathology changes (pyelitis, bile duct proliferation, bile pigment, etc.) in the 48 and 12 mg/kg/day dose groups. Based upon these findings, the NOEL for systemic effects is set at 1 mg/kg/day.

MCPA technical was fed to male and female rats for 3 months at dose levels of 0, 2.5, 7.5, and 22.5 mg/kg/day. The kidney was the major target organ based upon increased absolute and relative kidney weights in mid- and high-dose males, but not females. This was associated with a significant decrease in serum calcium in HDT males and a significant elevation in creatinine concentrations in HDT females. Both sexes had apparent crystalluria (oxalate, calcium phosphate, urate) in the high-dose groups, another possible indicator of kidney dysfunction. These findings in the kidney were not confirmed from histopathological evaluation, therefore the toxicological nature of MCPA on kidneys is unknown. Hepatotoxicity is also suggested in HDT males based upon prolongation in clotting times and decreased cholesterol concentrations. Based upon significant elevations in kidney weights (absolute, relative) at both the mid- and high-dose levels in male rats, the NOEL for systemic effects is set at 2.5 mg/kg/day.

No additional subchronic oral studies are required.

Subchronic Dermal (21-Day)

Sufficient data are not available for technical MCPA acid to fulfill the requirement for a 21-day dermal study. Since the existing acceptable uses of MCPA could result in repeated human skin contact of a limited frequency and duration, a study is required. However, since the existing acceptable uses of MCPA should not result in purposeful or prolonged exposure of the human skin, a 90-day dermal study is not required.

Subchronic Inhalation (90-Day)

A 90-day inhalation study for MCPA acid is not available. Since the existing acceptable end-uses (presently registered uses) should not result in repeated inhalation for extended periods, a subchronic inhalation study is not required.

Subchronic Neurotoxicity

A subchronic neurotoxicity test is not required since MCPA is not an organophosphate compound.

Chronic Toxicity

Sufficient data are available to satisfy the requirements for the chronic feeding studies in both species for technical MCPA acid. No further chronic toxicity data are needed for MCPA acid.

The oral administration of technical MCPA to male and female beagles at doses of 0, 0.15, 0.75, and 3.75 mg/kg for a period of 52 weeks resulted in kidney and liver toxicity at the mid- and/or high-dose levels with alterations in clinical chemistry or enzymes associated with concomitant organ weight changes (liver) and histopathology changes (kidney: proximal tubular epithelium; liver: change in nature of gall fluid). Therefore, based upon kidney and liver toxicity of a moderate nature at the 0.75 and 3.75 mg/kg dose levels, the systemic toxicity NOEL is set at 0.15 mg/kg/day, LDT.

Oral administration of MCPA (0, 1.0, 4.0, and 16.0 mg/kg/day) for two years in the diet of male and female Wister rats produced evidence of body weight depressions in males but not females; and hepato- and nephrotoxicity in both sexes at either the mid or high dose level. Hepatotoxicity was evident primarily in females; statistically significant elevations in triglycerides (mid dose tested (MDT), highest dose tested (HDT)) in both sexes, decreased cholesterol and increased clotting time in HDT females and increased SGPT levels (MDT/HDT) in females were observed. Nephrotoxicity was indicated by increased absolute and relative kidney weights in HDT females associated with an elevation in blood urea concentrations. In HDT males, gross pathology in the kidney was suggested by an increase in retraction and granularity of the kidneys associated with an increase in chronic progressive nephropathy. There was no evidence of an oncogenic response in either male or female rats treated with MCPA under the conditions of the bioassay. The systemic toxicity NOEL is set at the low dose level (1.0 mg/kg/day) for both males and females based upon the hepatotoxicity and nephrotoxicity observed in either the mid and/or high dose groups.

Oncogenicity

There are adequate studies available to satisfy the data requirements for oncogenicity studies in two species (rat, mouse).

The rat chronic toxicity study discussed above fulfills the requirement for the rat oncogenicity study. As stated above, there was no evidence of an oncogenic response in either male or female rats at the dose levels tested (1,4,16 mg/kg/day).

An acceptable 2 year oncogenicity study with B6C3F1 mice at dietary levels of 0, 3, 15, and 75 mg/kg/day was reviewed. MCPA is considered to be non-oncogenic under the conditions of the study.

Teratogenicity

Studies cited as acceptable in the original 1982 Registration Standard were found unacceptable upon rereview. In the rat teratology study cited in 1982, there was generally no evidence of compound related effects upon maternal or fetal health or development. However, due to technical deficiencies in the study, a developmental NOEL cannot be determined. In a rabbit teratology study relied on in 1982, increased maternal deaths at the HDT of 75 mg/kg associated with 100% resorptions were observed. There were no developmental alterations. Again, technical deficiencies in the study prevent determination of a developmental NOEL.

Teratology studies in two species are required.

Reproduction

There are sufficient data available to satisfy the data requirement for a reproductive study for technical MCPA.

In a two-generation reproduction study, MCPA was administered in the diets of adult rats at 0, 2.5, 7.5, and 22.5 mg/kg/day continuously from study initiation (at least 10 weeks prior to mating, throughout mating, gestation and lactation). Some consistent but slight depressions in pup body weight or body weight gains were observed at day 14 or day 21 in the high-dose group males and/or females of all littering groups (F1a, F1b, F2a, F2b). This is believed to be a result of direct toxicity of MCPA and not necessarily a reproductive effect, since the toxicity is not seen until later in the weaning period when the pups are being exposed to both the mothers' milk and dietary mix with MCPA also. However, a possible delayed postnatal growth effect cannot be ruled out.

Based upon the small but statistically significant depression in male and/or female pup weights/pup weight gains by days 14 and 21 of weaning in all littering groups (F1a, F1b, F2a, F2b), which may indicate a potential delayed postnatal growth effect, the NOEL is set at the mid-dose level of 7.5 mg/kg/day.

An additional reproduction study is not required.

Mutagenicity

There are sufficient data available to satisfy the mutagenicity requirements for structural chromosome aberrations and DNA damage and repair.

Gene Mutation. No acceptable study is available. A gene mutation study is required.

Structural Chromosomal Aberrations. After administration of single oral doses of 33, 200, and 1200 mg/kg MCPA to male and female Chinese hamsters, it was concluded that MCPA was not mutagenic in bone marrow cells (metaphase analysis) examined at 6, 24, and 48 hours post-administration. No additional structural chromosomal aberration studies on MCPA acid are required.

Other Genotoxicity; DNA Damage and Repair. After a single oral dose of MCPA at 1200 mg/kg to male and female Chinese hamsters, the test compound produced a statistically significant elevation (1.5 fold) in the number of sister chromatid exchanges (SCE) in bone marrow cells. It was concluded that MCPA was weakly mutagenic in this bioassay.

No additional genotoxicity studies on MCPA acid are required.

Metabolism

Sufficient data are available to meet the data requirements for a metabolism study with technical MCPA.

After a single oral dose (100 mg/kg) of ^{14}C-MCPA, the test material is excreted in the urine of male and female rats by 24 and 48 hours. Approximately 100 percent of the dose in either male or female rats (85.9% and 70.3% respectively) is absorbed after oral administration based upon radioactive recoveries at 192 hours (101.3 and 92.5%, respectively). MCPA does not appear to be significantly metabolized in vivo since it is the major component recovered in male and female rat urine (82 and 88%, respectively). Major organ/tissue sites are the plasma, liver, kidney, thyroid and stomach; fat and skin appear to sequester radiolabeled MCPA to a limited extent. Repeat dosing (1 mg/kg up to 14 days; once/day did not generally indicate bioaccumulation in any site except perhaps the kidney, primarily in males. As in the single dosing study, fat appeared to be the site of some MCPA sequestration.

An additional metabolism study is not required.

Special Neurotoxicity Testing

MCPA is structurally related to 2,4-D which is suspected of causing neuropathy in humans. Special neurotoxicity testing of 2,4-D is currently required. Because of this structural similarity to 2,4-D, the Agency is also requiring neurotoxicity testing of MCPA acid and its derivatives.

Toxicology Profile of Other MCPA Derivatives

The Agency has registered 12 salts, esters and amines of MCPA in addition to the acid. As stated previously, from a toxicological standpoint one may expect the acid and the sodium salt to be essentially identical. However, the remaining organic amines and esters may be significantly different and, lacking data to show otherwise, may be expected to have different qualitative and/or quantitative toxicological properties. The major exposure to these compounds is during application. Additional toxicology data are required on the organic amines and esters of MCPA (see Toxicology Data Tables Appendix I). The following is a listing of acceptable acute toxicity data avaiable for some of the derivatives:

Compound	Findings
Acute Oral	
MCPA butoxyethyl ester (95.5% purity)	LD_{50} is 1000 mg/kg in male rats and 785 mg/kg in female rats; acceptable data; Toxicity Category III
Acute Dermal	
MCPA butoxyethyl ester (95.5% purity)	LD_{50} = 2828 mg/kg (male rabbits); acceptable data; Toxicity Category III
Acute Inhalation	
MCPA butoxyethyl ester (95.5% purity)	LC_{50} > 4.2 mg/L/4 hours (rats, both sexes; acceptable data; Toxicity Category III
MCPA isooctyl ester (purity 95.1%)	LC_{50} > 4.4 mg/L/4 hours (rats, both sexes); acceptable data; Toxicity Category III
Primary Eye Irritation	
MCPA butoxyethyl ester (95.5% purity)	No eye irritation observed beyond 48 hours postinstillation (female rabbits); acceptable data; Toxicity Category III
Primary Skin Irritation	
MCPA butoxyethyl ester (95.5% purity)	Little evidence of skin irritation (male, female rabbits); acceptable data; Toxicity Category IV
Dermal Sensitization	
MCPA butoxyethyl ester (95.5% purity)	Not a potential skin sensitizer (male guinea pigs); acceptable data

Isooctyl ester of MCPA (48.6% MCPA acid equivalent)	May be a potential skin sensitizer (male guinea pigs); acceptable data
MCPA dimethylamine salt (43.3% MCPA acid equivalent)	Not a skin sensitizer (male guinea pigs); acceptable data

C. HUMAN EXPOSURE

The high volatility of MCPA esters increases the potential of respiratory exposure. Most salt formulations are essentially non-volatile. Spray drift, primarily from aerial spraying operations using ester formulations may lead to exposure of humans, livestock, wildlife, and crops outside of the application site. Most direct human exposure will be during mixing and loading operations. Exposure should be minimized by the wearing of appropriate protective equipment. From results of acute studies, the Agency has identified that protective eyewear is appropriate for mixers/loaders/applicators using the MCPA acid products. Use of protective eyewear is also required on homeowner use products that contain MCPA acid. No specialized protective language, other than those stated in 40 CFR 156 is warranted for other MCPA derivative homeowner use products.

Poisoning Incidents

The Pesticide Incident Monitoring System (PIMS) report does not contain any cases of hospitalization, or deaths in California or the nation. There have been no poisoning incidents with MCPA reported in California since 1974.

Reentry and Spray Drift

Based on available toxicology data, MCPA end-use products are of low acute toxicity, generally falling in Toxicity Category III. Therefore, reentry data are not required since MCPA does not meet the criteria for reentry data requirements given in 40 CFR 158.390 or spray drift data requirements given in 40 CFR 158.440.

D. OTHER SCIENCE FINDINGS

1. ENVIRONMENTAL FATE

Available data are insufficient to fully assess the environmental fate of MCPA and its various derivatives. An ester or amine derivative may behave differently in the environment than the MCPA acid. Data required on each derivative are indicated in the Environmental Fate data tables (see Appendix I). Data on MCPA acid will satisfy the data requirements for the MCPA sodium salt. Data on MCPA acid will be applicable to the amine salts and ester derivatives only if the registrants can show that the parent chemical dissociates or degrades from the salt or ester derivative to MCPA acid. Information on the rate and completeness of the dissociation or degradation reaction to the acid are essential to the development of an environmental fate profile for each registered MCPA chemical derivative.

A large number of studies were reviewed in the original MCPA Registration Standard, the majority of which were previously judged to be unacceptable. The 1982 document required studies on physical and chemical degradation, metabolism, field dissipation, and accumulation. In four study categories the Agency is now requiring more data than in the Registration Standard of 1982.

- The hydrolysis study requirement was previously judged to be partially fulfilled and is currently judged to be unacceptable because of study deficiencies including the fact that the test duration was only 13 days.

- The photolysis study requirement was previously listed as partially fulfilled in the original Registration Standard. However, this was not accurate because the study was not acceptable and all data were required.

- The leaching study requirement was fulfilled previously and is currently considered to be partially fulfilled. Additional studies are needed in addition to the previously submitted thin-layer chromatography (TLC) study to assess leaching potential. Furthermore, the adsorption/desorption category, which was listed in 1982 as a separate category, is currently grouped in the leaching and adsorption/desorption category.

- The aquatic field dissipation requirement was previously considered to be partially fulfilled, however that study would not currently be regarded as an aquatic field dissipation study and therefore is not acceptable.

Preliminary data have shown MCPA to degrade under laboratory aerobic conditions with a half-life ranging from less than a week to greater than 50 days. Two degradates included 4-chloro-o-cresol and 5-chloro-3-methylcatechol. Acceptable data on anaerobic aquatic metabolism demonstrated that 89 percent of the parent MCPA remained undegraded at 374 days. Preliminary data indicate that MCPA is stable to hydrolysis and to photolysis on soil. MCPA was found to be mobile as determined by soil TLC (R_f 0.6 to 1.0) in sandy loam, silt loam and silty clay loam, soils. The data are insufficient to fully assess leaching potential.

Preliminary field dissipation data indicate dissipation within the range found in the laboratory aerobic metabolism studies. Preliminary field aquatic dissipation data indicate that MCPA dissipates rapidly (14 to 21 days) in water, but persists unchanged in the flooded soil. No laboratory anaerobic soil metabolism data is available to help confirm these results. Preliminary forestry data indicate that MCPA is persistent in soil and leaf litter at 10 months posttreatment.

MCPA salts are highly soluble in water. The salts are considered to be somewhat less phytotoxic to crops than are the esters; however the esters are somewhat more effective on some perennial and woody weeds. The salts are less volatile than the esters.

Groundwater

MCPA appears to be mobile and was detected at a level ranging from 0.36 to 5.5 parts per billion (ppb) in 3 of 13 wells that were tested for multiple chemicals in Missouri. Groundwater contamination appears to be associated with point sources (mixing and loading sites). No special groundwater data, beyond that required in 40 CFR 158.290, are required at this time. Because of the above information and the chemical structure of MCPA, a special groundwater statement is being required (see Labeling Requirements section IV.D. in this document).

2. ECOLOGICAL EFFECTS

Available data are insufficient to completely evaluate the ecological effects of MCPA. The 1982 MCPA Registration Standard required a full battery of fish and wildlife testing on MCPA acid. In addition certain data were required on the derivatives of MCPA. Data, as set forth in the data tables (refer to Appendix I), are either required or reserved pending evaluation of required data. From an ecological effects standpoint, MCPA acid and the sodium salt are essentially equivalent. Therefore, ecological effects data available for the acid will support the sodium salt. Data on the MCPA acid will not support the data requirements for the ester or amine derivatives. The following conclusions can be made based on data available to the Agency:

Effects on Birds - Avian toxicity data are complete for MCPA acid. Data are required for all other MCPA derivatives. Studies on MCPA acid indicate an acute oral LD_{50} value of 377 mg/kg for bobwhite quail and dietary LC_{50} values of > 2000 ppm for the mallard, bobwhite, and ring-necked pheasant. These data incidate that MCPA acid is moderately toxic to avian species on an acute basis and practically nontoxic on a subacute dietary basis. These data are applicable to the sodium salt and fulfill the data requirements for these studies for both the technical acid and the sodium salt.

Effects on Fish Freshwater Fish - Ecotoxicity studies indicate that MCPA acid is slightly toxic to freshwater fish on an acute basis (rainbow trout LC_{50} = 89 ppm, bluegill sunfish

LC_{50} = 97 ppm). Toxicity studies on the sodium salt derivative indicate that this compound is practically nontoxic to fish (LC_{50} values > 180 ppm). These studies fulfill the warmwater and coldwater fish LC_{50} study requirements of the sodium salt formulations. A rainbow trout study on the dimethylamine salt derivative indicates that this compound is practically nontoxic to coldwater fish species (LC_{50} = 117 ppm). This study fulfills the coldwater fish LC_{50} requirement of the technical dimethylamine salt. Additional data on the various MCPA derivatives are required.

Effects on Freshwater Invertebrates - A study on daphnids using MCPA acid showed practically no toxicity to aquatic freshwater invertebrates (LC_{50} > 180 ppm). Acute LC_{50} testing on freshwater aquatic invertebrates is required for the various MCPA derivatives. In addition, product testing using the sodium salt is required to support the registered aquatic use.

Effects on Estuarine and Marine Organisms - Toxicity studies indicate that MCPA acid is practically nontoxic to estuarine and marine organisms (Atlantic Silverside LC_{50} = 179 ppm; Oyster larvae LC_{50} = 155 ppm). Additional testing is required in shrimp for the acid of MCPA. A complete battery of tests are required for the various MCPA derivatives. Formulated product testing using the sodium salt is required to support the registered aquatic use.

Effects on Plants - All MCPA derivatives are labeled to control a variety of broadleaf weeds. MCPA salts are highly soluble in water. The salts are considered to be somewhat less phytotoxic to crops than are the esters; however the esters are somewhat more effective on some perennial and woody weeds. The salts are less volatile than the esters.

The Agency has no acceptable data for toxicity of nontarget plants. A complete battery of tests are required for MCPA acid and each derivative.

Risk to Nontarget Organisms (Including Endangered Species) - Due to limited environmental fate and ecological effects data, complete hazard assessments cannot be conducted at this time.

Because of MCPA's demonstrated toxicity to nontarget species and its intended use pattern, this pesticide has been identified by the Office of Endangered Species (OES), U.S. Fish and Wildlife Service (USFWS), as being likely to jeopardize the continued existence of certain endangered species when used on range, pastureland, corn, wheat, sorghum, oats, barley, and/or rye. Based on this determination, OES specified reasonable and prudent alternatives to avoid jeopardizing the continued existence of the identified species by these uses. EPA is working with the FWS and other Federal and State agencies to implement the alternatives in a technically sound matter. The Agency has initiated a comprehensive plan for protecting endangered species. This program was announced in the Federal Register Vol. 54(126) on Monday, July 3, 1989. The program includes a new approach to biological consultation and a revised implementation plan, including a voluntary Interim Program. Registrants are to refer to the Federal Register notice for greater details.

Nontarget Insects - There is sufficient information to characterize MCPA acid and its sodium salt derivative as relatively nontoxic to honey bees, when bees are exposed to direct treatment. Bee toxicity data are not required for the butyl ester, isobutyl ester and isopropyl ester because there are no registered outdoor uses; for the diethanolamine salt and butoxyethyl ester there is low potential for bee exposure and no data are required; there is significant potential for bee exposure to the dimethylamine salt and isooctyl ester and data are required for these last two derivatives.

3. PRODUCT CHEMISTRY

The data tables in Appendix I go into greater detail for specific data requirements. The Agency has determined that product chemistry data for all technical and manufacturing-use products must be resubmitted for each pesticide because new requirements have been introduced since the issuance of the Registration Standard in 1982. Up until 1982, no registrant of a product containing MCPA or an MCPA derivative had submitted a detailed manufacturing process, a discussion of the formation of unintentional substances in the product, a declaration and certification of ingredient limits, or analytical data on the product. For many products, a confidential statement of formula had not been submitted, was outdated, incomplete or in error. Data on numerous physical and chemical properties had not been submitted. The Agency is now requiring that previously submitted data be updated.

The Agency has noted, as it did in the 1982 document, that MCPA may be contaminated with dioxins or dibenzofurans, and that the amine salts of MCPA may be contaminated with n-nitrosamines. Analytical data to identify and quantify these contaminants are required for certain products (refer to Product Chemistry Data Requirement Tables in Appendix I).

E. TOLERANCE ASSESSMENT

Only plant metabolism data were required to support the established tolerances for residues in or on plant or animal commodities in the Registration Standard issued in March 1982. However, additional data gaps have been identified as a result of residue chemistry guidelines issued in 1982 and other policy changes since that time.

Tolerances for residues in or on food and feed plant commodities are currently expressed in terms of MCPA per se (40 CFR 180.339(a)) and tolerances for residues in or on animal commodities are expressed in terms of combined negligible residues of MCPA and its metabolite 2-methyl-chlorophenoxyacetic acid (40 CFR 180.339(b)). EPA has evaluated the residue and toxicology data supporting these tolerances. The following were considered during this evaluation:

- Whether the current tolerances and food additive regulations are sufficient to cover the actual residues resulting from use (including FIFRA section 24(c) registrations).
- Whether group tolerances can be established in accordance with 40 CFR 180.34(f).
- Whether, in the absence of tolerances, restrictions on use, grazing, or feeding of treated commodities are necessary.
- Whether the tolerances are expressed accurately and in current terminology.

The Agency's findings as a result of this evaluation are summarized below. The regulatory results of the Agency's review are set out in Section IV, Regulatory Position and Rationale.

Residue Data

The residue data reviewed in support of these tolerances showed the following:

1. Data on the metabolism of MCPA in plants available for review in the 1982 document indicated that MCPA is readily taken up and translocated by plants. Additional data are required on the identity and quantities of residue in or on plants. The nature of the residue is not adequately understood.

2. Data pertaining to the residues of MCPA in animals were reviewed for the 1982 document. That document did not require additional data on animal metabolism. Current Guidelines specify that terminal residues in animals be identified and quantified using radioactive material. The metabolism of MCPA in animals is not adequately understood and additional data are required.

3. The current residue analytical methods in PAM I are adequate for enforcement of tolerances for residues in plants and animals.

4. Data depicting the stability of MCPA residues in storage were not required in the 1982 document. Current Guidelines

specify that storage stability data must be submitted in support of established tolerances.

5. There are available data to support the established tolerances for MCPA in or on canarygrass seed and straw.

6. Additional residue data are required on dried beans, peas (succulent and dry), pea vines and hay, rice grain, sorghum grain, wheat grain, rice straw, sorghum forage and fodder, wheat straw, annual canarygrass, pasture and rangeland grasses, grass hay, alfalfa and alfalfa hay, flaxseed, and flax straw.

7. The data requested on wheat grain, forage, and straw may, by translation, support the established tolerances for residues of MCPA in or on the grain, forage, and straw of barley, oats, and rye. The data requested on alfalfa and alfalfa hay may, by translation, support the established tolerances for residues of MCPA in or on clover and clover hay, lespedeza and lespedeza hay, trefoil and trefoil hay, and vetch and vetch hay.

8. Processing data are needed on rice grain, sorghum grain, wheat grain, and flaxseed. The requirements for processing data on barley, oat, and rye grain may be satisfied by the data requested on wheat.

9. Tolerances need to be proposed for residues of MCPA in or on bean vines and hay, barley hay, oat hay, rye hay, wheat forage and hay, and canarygrass forage.

10. Upon receipt of the data requested on animal metabolism and livestock feed items, the established tolerances for the combined residues of MCPA and 2-methyl-4-chlorophenol in the meat, fat, and meat by-products of cattle, goats, hogs, horses, and sheep and in milk will be assessed and the need for tolerances for residues in poultry tissues and eggs will be determined.

Toxicology Data

A provisional acceptable daily intake (PADI, RfD) of 0.0015 mg/kg/day for MCPA has been established based on a 1-year feeding study (dog, NOEL 0.15 mg/kg). The value given is a PADI because of the teratology data gaps. However, when the teratology studies are submitted and found acceptable, they are not expected to greatly alter the RfD calculations. A safety factor of 100 was utilized. The dietary exposure was calculated using the published tolerances in 40 CFR 180.339. A dietary exposure for the U.S. population is calculated to be 0.001547 mg/kg/day, corresponding to 103 percent of the RfD. The population subgroups with the highest calculated exposure were nonnursing infants (0.007405 mg/kg/day, 493% of the RfD) and children 1 to 6 years of age (0.004069 mg/kg/day, 271% of the RfD). A dietary exposure was also conducted using the published tolerances factored by the percent of crop treated with MCPA. The dietary exposure for the U.S. population is then 10% of the RfD, for nonnursing infants, 51% of the RfD, and for children 1 to 6 years of age, 27% of the RfD.

IV. REGULATORY POSITION AND RATIONALE

A. Regulatory Positions and Rationales

Based on the review and evaluation of available data on MCPA, the Agency has made the following determinations. Where label revisions are imposed, specific language is set forth in the labeling section of this chapter.

1. The Agency will not place MCPA in Special Review at this time.

Rationale. Based on the data available to the Agency, MCPA has not met or exceeded any of the risk criteria specified in 40 CFR 154.7 to initiate a Special Review. The Agency will evaluate potential risks as additional data become available and will consider additional regulatory action, if applicable.

2. The Agency will not restrict the use of MCPA products to certified applicators.

Rationale. Based on available data, MCPA products have not met or exceeded any of the criteria specified in 40 CFR 152.170 which would indicate a need to restrict its use.

3. The Agency will require data on the acid, sodium salt, amines, and esters of MCPA as reflected in the data tables of this document and as previously required in the 1982 MCPA Registration Standard.

Rationale. When MCPA is formulated as an ester or amine, the physical characteristics, biological activity and fate in the environment may be affected. The Agency has little or no data to evaluate the effects of the ester or amine derivatives of MCPA. Data on each salt, ester and amine derivative are needed to allow evaluation of these forms of MCPA.

4. The Agency is requiring precautionary labeling to minimize any potential hazard to nontarget organisms.

Rationale. Certain formulations of MCPA are toxic to fish and/or aquatic invertebrates. Precautionary labeling will reduce any potential risks to these organisms from the use of MCPA.

5. The OES in the USFWS has determined the use of MCPA may

jeopardize the continued existence of endangered species or critical habitat of certain endangered species. The Agency has initiated an Endangered Species Protection Program. That program was announced in the Federal Register of July 3, 1989 (54 FR 27984). No additional labeling is being required at this time.

Rationale. In May 1987, EPA issued PR Notices 87-4 and 87-5 in response to OES findings that certain pesticides, including this chemical, jeopardized the continued existence of endangered species. Those PR Notices directed registrants to add labeling to their products which referred users to additional information that, in turn, explained limitations on use of the pesticide within the range of jeopardized endangered species. Subsequent to issuance of these PR Notices, EPA identified a number of significant technical errors and inconsistencies in the information to which users would have been referred. Therefore, on January 26, 1988, the Agency issued PR Notice 88-1 which withdrew PR Notices 87-4 and 87-5 pending development of a more focused program to protect endangered species.

The proposed comprehensive program includes a new approach to biological consultation and a revised implementation plan, including a voluntary Interim Program. Consult the Federal Register notice for details of the new program. When that program is fully developed, registrants will be notified of any labeling statements imposed on MCPA products that the Agency found necessary to protect endangered species.

6. The Agency is requiring a groundwater warning statement on the labels of MCPA products.

Rationale. Residues of MCPA have been detected in groundwater, mostly from point sources, such as mixing, loading and disposal sites. Since MCPA could be a potential groundwater contaminant, a label statement will advise users to exercise caution when handling MCPA products to prevent such contamination.

The Agency is currently finalizing its Agricultural Chemicals in Groundwater Strategy and its policy for restricting the use of pesticide products which may reach groundwater. When the policies are in place, the Agency will consider what action is appropriate for MCPA products and other products containing ingredients which may reach groundwater.

7. The Agency is not requiring a reentry interval for MCPA products.

Rationale. Based on the toxicological data available to the Agency, MCPA products have a low acute oral, acute dermal, and acute inhalation toxicity (Toxicity Categories III and IV).

Because of these low acute toxicity levels, it is not necessary to establish a reentry interval.

8. The Agency is requiring protective clothing (eye protection) labeling for MCPA acid product for mixers, loaders, and applicators.

Rationale. Based on technical MCPA acid product data, the MCPA acid is Toxicity Category I for eye irritation. Mixers, loaders, and applicators are required to wear eye protection equipment. Homeowner use products containing MCPA acid have been placed in Toxicity Category I for eye irritation and will also require the wearing of eye protection equipment. Registrants must submit acute eye irritation data to support any request to change this toxicity category for homeowner use products. Refer to the required labeling section IV C. in this document and precautionary labeling language found in 40 CFR 156.

9. The Agency will consider establishment of significant new food use tolerances for MCPA.

Rationale. While the current residue chemistry and toxicology data are not sufficient to assess all existing tolerances, the current calculated dietary exposure factored by the percent of crop treated for nonnursing infants (this group has the highest potential exposure to MCPA residues) is 51% of the Rfd. The Agency will consider registering significant new food/feed uses when data are available to establish a more complete human dietary exposure data base.

10. The Agency will assess the adequacy of the tolerances for residues of MCPA in milk, and in meat, fat, and meat byproducts of cattle, hogs, horses, and sheep upon receipt and evaluation of required data.

Rationale. Numerous data gaps exist pertaining to the data requirements on livestock feed items. Further, the metabolism of MCPA in animals is not adequately understood.

11. The Agency will require that tolerances be proposed for the raw agricultural commodities bean vines and hay, barley hay, oat hay, wheat forage and hay, and canarygrass forage OR all pertinent product labels may be amended to impose a restriction of the feeding of these commodities to livestock.

Rationale. Tolerances have not been proposed or established for residues of MCPA that occur from its use on these commodities.

12. The Agency is deleting the entry in 40 CFR 180.339(a) of "vegetables, seed and pod." The Registrant must propose appropriate individual commodity tolerances.

Rationale. There are insufficient data to support a group tolerance for vegetables at this time. Since a group tolerance is not appropriate at this time, the individual tolerances of the various commodities must be expressed.

13. The Agency is requiring that additional residue data be submitted for residues of MCPA in or on dried beans, peas (succulent and dry), soybeans, pea vines and hay, wheat grain, rice grain, sorghum grain, wheat straw, rice straw, canary grass forage, pasture grass forage and hay, alfalfa, alfalfa hay, and flaxseed and flax straw.

Rationale. While data on many of these commodities were not required in the previous Registration Standard, it is now determined that the data pertaining to residues of MCPA in or on these crops were inadequate.

14. The Agency is requiring processing data for rice grain, sorghum grain, wheat grain, and flaxseed.

Rationale. Data are unavailable to assess whether additional tolerances are required in the processed commodities of these crops.

15. The Agency is requiring storage stability data of MCPA residues.

Rationale. While not required in the 1982 document, current Guidelines (Subdivision O) specify that all data submitted in support of established tolerances must be validated by adequate storage stability data.

16. The Agency is requiring that the registrant propose a pertinent product label preharvest interval (PHI) for peas (succulent and dry), beans (succulent and dry), rice grain, sorghum grain, wheat grain, rice straw, sorghum forage and fodder, wheat straw alfalfa, alfalfa hay, clover forage and hay, flaxseed and flax straw. The Agency is also requiring that the preslaughter intervals (PSI) be deleted from labels for pastureland and pasture grass. The Registrant must propose pregrazing intervals (PGI) for canary grass, flax seed and straw, and alfalfa hay and forage.

Rationale. Directions on labels of products registered for these uses do not contain appropriate PHI's, PSI's, and PGI's. These intervals must be supported by data submitted to the Agency.

17. EPA is requiring information on the manufacturing process for MCPA products in order to evaluate whether contamination with tetra- through heptahalogenated dibenzo-p-dioxins or dibenzofurans occurs. Analysis of the amine salts of

MCPA for n-nitrosamines is required.

Rationale. Polyhalogenated dibenzo-p-dioxins or dibenzofurans may be formed during manufacture of MCPA and N-nitrosamines may be formed during manufacture or storage of MCPA. The Agency has identified these contaminants as being toxicologically significant. The Agency does not have sufficient data to determine the extent and significance of the contamination.

18. The Agency will immediately review certain data as they are submitted.

Rationale. Because of concerns regarding potential risks from MCPA use, the Agency believes it is essential that the following data be reviewed as they are received: Information on the manufacturing process to assess potential dioxin and furan formation, as well as nitrosamine analysis of the amine salts of MCPA, groundwater contamination potential data, and the teratology studies.

19. While data gaps are being filled, currently registered manufacturing-use products (MPs) and end-use products (EPs) containing MCPA may be sold, distributed, formulated, and used, subject to the terms and conditions specified in this Standard. However, significant new uses (including new food/feed uses) will not be registered. Registrants must provide or agree to develop additional data, as specified in the data tables in order to maintain existing registrations.

Rationale. Under FIFRA, the Agency may elect not to cancel or withhold registration even though data are missing or are inadequate (see FIFRA section 3(c)(2)(B) and 3(c)(7)). Issuance of this Standard provides a mechanism for identifying data needs. These data will be reviewed and evaluated, after which the Agency will determine if additional regulatory actions are necessary. Because of the quantity of data required to maintain existing registrations, the Agency has elected not to consider registration of any significant new uses (including new food/feed uses) while data gaps are being filled and data evaluated.

B. Criteria for Registration

To be registered or reregistered under this Standard, products must contain MCPA, bear required labeling, and conform to the product composition, acute toxicity limits, and use pattern requirements listed in this document.

C. Acceptable Ranges and Limits

Product Compositions Standard. To be registered or reregistered under this Standard, MPs must contain MCPA. Each MP formulation proposed for registration must be fully described with an appropriate certification of limits, stating maximum and minimum amounts of the active ingredient and inert ingredients which are present in products, as well as impurities found at greater than 0.1 percent.

Acute Toxicity Limits. The Agency will consider registration of technical grade and MPs containing MCPA provided that the product labeling bears appropriate precautionary statements for the acute toxicity category in which each product is placed.

Use Patterns. To be registered under this Standard, MPs may be labeled for formulation into EPs bearing federally registered uses. The EPA Index to Pesticide Chemicals (for availability, see page 1) lists all federally registered uses of this pesticide ingredient, as well as approved maximum application rates and frequencies.

The use patterns currently registered are terrestrial (food and nonfood); aquatic (food and nonfood); domestic; and forestry.

D. Labeling

In order to remain in compliance with FIFRA, products must bear appropriate labeling as specified in 40 CFR 156.10 and this Standard, or must be revised to conform to those specifications. Appendix II contains information on label requirements.

No pesticide product containing this pesticide may be released for shipment by the registrant after October 1990 unless the product bears amended labeling that complies with the requirements of this Standard.

No pesticide products containing this pesticide may be distributed or sold after October 1991 unless the product bears an amended label which complies with the requirements of this Standard.

The following specific information must appear on the labeling in order for products to remain in compliance with FIFRA:

1. Ingredient Statement. The ingredient statement for products must list the active ingredient as:

2-methyl-4-chlorophenoxyacetic acid . . . . ____%

The ingredient statement for MCPA derivative products must list the active ingredient and the equivalent percentage of MCPA, for example:

2-methyl-4-chlorophenoxyacetic acid, sodium salt. . . . ____%
(Equivalent to ___% of 2-methyl-4-chlorophenoxyacetic acid)

2. Use Pattern Statements. All MPs must state that they are intended for formulation into EPs for acceptable use patterns. Labeling must specify sites, which are listed in Use Patterns, Section C.3. However, no use may be included on the label where the registrant fails to agree to comply with the data requirements in Table A for that use pattern.

3. Precautionary Statements.

For MCPA products, as appropriate, the following precautionary statements are required.

Manufacturing-Use Products

> "Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public waters unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance, contact your local State Water Board or Regional Office of the EPA."

End-Use Products

Protective Clothing Statement: For MCPA acid formulations - (This statement does not apply to homeowner use products):

> "Mixers/loaders/applicators are required to use face shields or goggles."
>
> For homeowner MCPA acid products:
>
> "When mixing or applying this pesticide, use of a face shield or goggles is required."

Environmental Hazard Statement:

> "Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters or rinsate."

Ground Water Contamination Statement - On all Products:

> "Although highly mobile, in general, phenoxy herbicides such as MCPA are not sufficiently persistent to reach ground water from use as specified on product label. Most cases of ground water contamination involving phenoxy herbicides have been associated with mixing/loading and disposal sites. Do

> not contaminate water supplies when handling or using MCPA pesticide products."

Cleaning of Equipment Statement: Products that require mixing prior to application must have the following statement:

> "Cleaning of Equipment: When cleaning equipment, do not pour washwater on the ground; spray or drain over a large area away from wells and other water sources."

4. Disposal Statements

Certain unused MCPA stocks are listed as toxic hazardous waste under the Resource Conservation and Recovery Act (RCRA); others may be hazardous waste because of their chemical or physical characteristics. The following is the appropriate pesticide disposal statement for all MCPA products, except those labeled for household use only:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate, is a violation of Federal law and may contaminate groundwater. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

The labels of all products must bear the appropriate container disposal statement (see Appendix II).

5. Product Specific Label Restrictions.

To be placed on the labels of EUP's when appropriate:

> "Do not use MCPA butoxyethyl ester in greenhouses, on heavy clay soils or where crops will be planted in a rough, cloddy seed bed."
>
> "Do not apply MCPA diethanolamine or MCPA isooctyl ester by aerial application in the vicinity of sugar beets"
>
> "Do not apply MCPA isooctyl ester around houses, recreation sites, or similar areas."
>
> "Do not apply MCPA sodium salt with nozzles that produce a fine spray."
>
> "Do not grow crayfish or catfish in treated rice fields."

Nontarget Plant Species Precautionary Statements:

For products with aquatic uses, use the following statement:

> "Drift or run-off may adversely affect nontarget plants. Do not apply directly to water except as specified on this label. Do not contaminate water when disposing of equipment washwaters."

For all other products use the following statement:

> "Drift or run-off may adversely affect nontarget plants. Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters."

V. PRODUCTS SUBJECT TO THIS STANDARD

All products containing one or more of the pesticides identified in Section II.A. are subject to certain requirements for data submittal or changes in composition, labeling or packaging of the product. The applicable requirements depend on whether the product is a manufacturing or end use product and whether the pesticide is the sole active ingredient or one of multiple active ingredients.

Products are subject to this Registration Standard as follows:

A. Manufacturing use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.
2. The data requirements listed in Tables A and B[1]
3. The labeling requirements specified for manufacturing use products in Section IV.
4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

B. Manufacturing use products containing this pesticide as one of multiple active ingredients are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV, if they pertain to the manufacturing use product.

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[1] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products.

2. The data requirements listed in Tables A and B[2]

3. The labeling requirements specified for manufacturing use products in Section IV.

4. Administrative requirements (application forms, Confidential Statement of Formula, data compensation provisions) associated with reregistration.

C. End use products containing this pesticide as the sole active ingredient are subject to:

1. The restrictions (if any) upon use, composition, or packaging listed in Section IV if they pertain to the end use product.

2. If eligible for the generic data exemption[3], the data requirements listed in Table C.

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[2] Data requirements are listed in the three Tables in Appendix I of this Registration Standard. The Guide to Tables in that Appendix explains how to read the Tables.

Table A lists generic data requirements applicable to all products containing the pesticide subject to this Registration Standard. Table B lists product-Specific data applicable to manufacturing-use products. The data in Tables A and B need not be submitted by an end-use producer who is eligible for the generic data exemption for that active ingredient.

Table C lists product-specific data applicable to end-use products.

[3] If you purchase from another producer and use as the source of your active ingredient only EPA-registered products, you are eligible for the generic data exemption for generic data concerning that active ingredient (Table A) and product-specific data for the registered manufacturing use product you purchase (Table B).

Two circumstances nullify this exemption:

1) If you change sources of active ingredient to an unregistered product, formulate your own active ingredient, or acquire your active ingredient from a firm with ownership in common with yours, you individually lose the exemption and become subject to the data requirements in Table A.

2) If no producer subject to the generic data requirements in Table A agrees to submit the required data, all end-use producers lose the exemption, and become subject to the data requirements in Table A.

3. If not eligible for the generic data exemption, the data requirements listed in Table A and the data requirements listed in Table C.

4. The labeling requirements specified for end use products in Section IV.

D. End use products containing this pesticide as one of multiple active ingredients are subject to:

1. If not eligible for the generic data exemption, the data requirements listed in Tables A and C.

2. If eligible for the generic data exemption, the data requirements listed in Table C.

3. The labeling requirements specified for end use products in Section IV.

VI. REQUIREMENT FOR SUBMISSION OF GENERIC DATA

This portion of the Registration Standard is a notice issued under the authority of FIFRA sec. 3(c)(2)(B). It refers to the data listed in Table A, which are required to be submitted by registrants to maintain in effect the regis-tration of products containing this active ingredient.[4]

A. What are generic data?

Generic data pertain to the properties or effects of a particular active ingredient. Such data are relevant to an evaluation of all products containing that active ingredient regardless of whether the product contains other ingredients (unless the product bears labeling that would make the data requirement inapplicable).

Generic data may also be data on a "typical formulation" of a product. "Typical formulation" testing is often required for ecological effects studies and applies to all products having that formulation type. These are classed as generic data, and are contained in Table A.

B. Who must submit generic data?

All current registrants are responsible for submitting generic data in response to a data request under FIFRA sec. 3(c)(2)(B) (DCI Notice). EPA has decided, however, not to require a registrant who qualifies for the formulator's exemption (FIFRA sec. 3(c)(2)(D) and 40 CFR 152.85) to submit generic data in response to a DCI notice if the registrant who supplies the active ingredient in his product is complying with the data request.

If you are granted a generic data exemption, you rely on the efforts of other persons to provide the Agency with the required data. If the registrants who have committed to generate and submit the required data fail to take appropriate steps to meet the requirements or are no longer in compliance with this data requirements notice, the Agency will consider that both they and you are not in compliance and will normally initiate proceedings to suspend the registrations of both your product(s) and their product(s) unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

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[4] Registrations granted after issuance of this Standard will be conditioned upon submittal or citation of the data listed in this Registration Standard.

If you are not now eligible for a generic data exemption, you may qualify for one if you change your source of supply to a registered source that does not share ownership in common with your firm. If you choose to change sources of supply, the Confidential Statement of Formula must identify the new source(s) and you must submit a Generic Data Exemption Statement.

If you apply for a new registration for products containing this active ingredient after the issuance of this Registration Standard, you will be required to submit or cite generic data relevant to the uses of your product if, at the time the application is submitted, the data have been submitted to the Agency by current registrants. If the required data have not yet been submitted, any new registration will be conditioned upon the new registrant's submittal or citation of the required data not later than the date upon which current registrants of similar products are required to provide such data. See FIFRA sec. 3(c)(7)(A). If you thereafter fail to comply with the condition of that registration to provide data, the registration may be cancelled (FIFRA sec. 6(e)).

C. What generic data must be submitted?

You may determine which generic data you must submit by consulting Table A. That table lists the generic data needed to evaluate current uses of all products containing this active ingredient, the uses for which such data are required, and the dates by which the data must be submitted to the Agency.

D. How to comply with DCI requirements.

Within 90 days of your receipt of this Registration Standard, you must submit to EPA a completed copy of the form entitled "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1, enclosed) for each of your products. On that form you must state which of the following six methods you will use to comply with the DCI requirements:

1. You will submit the data yourself.

2. You have entered into an agreement with one or more registrants to jointly develop (or share in the cost of developing) the data, but will not be submitting the data yourself. If you use this method, you must state who will submit the data on which you will rely. You must also provide EPA with documentary evidence that an agreement has been formed which allows you to rely upon the data to be submitted. Such evidence may be: (1) your letter offering to join in an agreement and the other registrant's acceptance of your offer, (2) a written statement by the parties that an agreement exists, or (3) a written statement by the person who will be submitting the data that you may rely upon its submittal. The Agency will also

require adequate assurance that the person whom you state will provide the data is taking appropriate steps to secure it. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or a mechanism to resolve the terms.

If you and other registrants together are generating or submitting requested data as a task force or consortium, a representative of the group should request a Joint Data Submitter Number, as part of your 90-day response. The request must include the following information:

a. A list of the members of the consortium;
b. The name and address of the designated representative of the consortium, with whom EPA will correspond concerning the data;
c. Identity of the Registration Standard containing the data requirement;
d. A list of the products affected (from all members of the consortium); and
e. Identification of the specific data that the consortium will be generating or submitting.

The Agency will assign a number to the consortium, which should be used on all data submittals by the consortium.

3. You have attempted to enter into an agreement to jointly develop data, but no other registrant has accepted your offer. You request that EPA not suspend your registration for non-compliance with the DCI. EPA has determined that, as a general policy, it will not suspend the registration of a product when the registrant has in good faith sought and continues to seek to enter into a data development/cost sharing program, but the other registrants developing the data have refused to accept its offer. [If your offer is accepted, you may qualify for Option 2 above by entering into an agreement to supply the data.]

In order to qualify for this method, you must:

a. File with EPA a completed "Certification of Attempt to Enter into an Agreement with other Registrants for Develop-ment of Data" (EPA Form 8580-6, enclosed).

b. Provide us with a copy of your offer to the other registrant and proof of the other registrant's receipt of your offer (such as a certified mail receipt). Your offer must, at a minimum, contain the following language or its equivalent:

> [Your company name] offers to share in the burden of producing the data required pursuant to FIFRA sec.3(c)(2)(B) in the [name of active ingredient] Registration Standard upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA
> section 3(c)(2)(B)(iii).

The remainder of your offer may not in any way attempt to limit this commitment. If the other registrant to whom your offer is made does not accept your offer, and if the other registrant informs us on a DCI Summary Sheet that he will develop and submit the data required under the DCI, then you may qualify for this option. In order for you to avoid suspension under this method, you may not later withdraw or limit your offer to share in the burden of developing the data.

In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice in a timely manner. If the other registrant fails to develop the data or for some other reason would be subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit and submit the required data in the specified timeframe. In such cases, the Agency generally will not grant a time extension for submitting the data.

4. You request a waiver of the data requirement. If you believe that a data requirement does not (or should not) apply to your product or its uses, you must provide EPA with a statement of the reasons why you believe this is so. Your statement must address the specific composition or use factors that lead you to believe that a requirement does not apply. Since the Agency has carefully considered the composition and uses of pesticide products in determining that a data require-ment applies, EPA does not anticipate that many waivers will be granted. A request for waiver does not extend the time-frames for developing required data, and if your waiver request is denied, your registration may be suspended if you fail to submit the data. The Agency will respond in writing to your request for a waiver.

5. You request that EPA amend your registration by deleting the uses for which the data are needed. You are not required to submit data for uses which are no longer on your label.

6. You request voluntary cancellation of the registration of your product(s) for which the data are needed.

E. Registrant Requests Regarding Data Requirements and Agency Responses

All requests for modification of data requirements (inapplicability, waiver), approval of protocols or protocol changes, or time extensions must be submitted in writing. The original requirement remains in effect unless the Agency has notified you in writing that it has agreed to a change in the requirement. While being considered by the Agency, such requests for changes in the requirements do not alter the original requirements or extend the time allowed for meeting the requirement.

F. Test Protocols and Standards

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines, unless other protocol or standards are approved for use by the Agency in writing. All testing must be conducted in accordance with applicable Good Laboratory Practices regulations in 40 CFR Part 160.

The Pesticide Assessment Guidelines, which are referenced in the Data Tables, are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, VA 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (Part 158.70). Please note, however, that certain OECD standards (such as test duration, selection of test species, and degradate identification which are environmental fate requirements) are less restrictive than those in the EPA Assessment Guidelines listed above. When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of Part 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accord with acceptable standards. The OECD protocols are available from OECD, 1750 Pennsylvania Avenue, N.W., Washington, D.C. 20006.

G. Procedures for requesting a change in test protocol.

If you will generate the required data and plan to use test procedures which deviate from EPA's Pesticide Assessment Guidelines or the Reports of Expert Groups to the Chemicals Group, Organization for Economic Cooperation and Development (OECD) Chemicals Testing Programme, you must submit for EPA approval the protocols you propose to use.

You should submit your protocols before beginning testing, because the Agency will not ordinarily accept as sufficient studies using unapproved protocols. A request for protocol approval will not extend the timeframe for submittal of the data, nor will extensions generally be given to conduct studies due to submittal of inappropriate protocols. The Agency will respond in writing to your request for protocol approval or change.

H. Procedures for requesting extensions of time.

If you think that you will need more time to generate the data than is allowed by EPA's schedule, you may submit a request for an extension of time.

EPA will view failure to request an extension before the data submittal response deadline as a waiver of any future claim that there was insufficient time to submit the data. While EPA considers your request, you must strive to meet the deadline for submitting the data.

The extension request should state the reasons why you believe that an extension is necessary and the steps you have taken to meet the testing deadline. Time extensions normally will not be granted due to problems with laboratory capacity or adequacy of funding, since the Agency believes that with proper planning these can be overcome. The Agency will respond in writing to any requests for extension of time.

I. Data Format and Reporting Requirements

All data submitted in response to this Notice must comply with EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or contained in PR Notice 86-5 (issued July 29, 1986). All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submittal requirement.

J. Existing stocks provision upon suspension or cancellation.

The Agency has determined that if a registration is suspended for failure to respond to a DCI request under FIFRA sec. 3(c)(2)(B), an existing stocks provision for the registrant is not consistent with the Act. Accordingly, the Agency does not anticipate granting permission to sell or distribute existing stocks of suspended product except in rare circumstances. If you believe that your product will be suspended or cancelled and that an existing stocks provision should be granted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. The following information must be included in any request for an existing stocks provision:

1. Explanation of why an existing stocks provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale or distribution; and

2. Demonstration that such a provision would be consistent with the provisions of FIFRA.

VII. REQUIREMENT FOR SUBMISSION OF PRODUCT-SPECIFIC DATA

Under its DCI authority, EPA has determined that certain product-specific data are required to maintain your registrations in effect. Product-specific data are derived from testing using a specific formulated product, and, unlike generic data, generally support only the registration of that product. All such data must be submitted by the dates specified in this Registration Standard.

If you have a manufacturing use product, these data are listed in Table B. If you have an end use product, the data are listed in Table C. As noted earlier, the Agency has decided that it will not routinely require product-specific data for end use products at this time. Therefore, Table C may not be contained in this Registration Standard; if there is no Table C, you are not required to submit the data at this time.

In order to comply with the product specific data requirements, you must follow the same procedures as for generic data. See Section VI.D through J. You should note, however, that product chemistry data are required for every product, and the only acceptable responses are options VI.D.1. (submit data) or VI.D.6.(cancellation of registration).

Failure to comply with the product-specific data require-ments for your products will result in suspension of the product's registration.

VIII. REQUIREMENT FOR SUBMITTAL OF REVISED LABELING

FIFRA requires each product to be labeled with accurate, complete and sufficient instructions and precautions, reflecting the Agency's assessment of the data supporting the product and its uses. General labeling requirements are set out in 40 CFR 156.10 (see Appendix II - LABELING and SUMMARY). In addition, labeling language specific to products containing this pesticide is specified in Section IV.D of this Registra-tion Standard. Responses to this Registration Standard must include draft labeling for Agency review.

Labeling must be either typewritten text on 8-1/2 x 11 inch paper or a mockup of the labeling suitable for storage in 8-1/2 x 11 files. Draft labeling must indicate the intended colors of the final label, clear indication of the front panel of the label, and the intended type sizes of the text.

If you fail to submit revised labeling as required, which complies with 40 CFR 156.10 and the specific instructions in Section IV.D., EPA may seek to cancel the registration of your product under FIFRA sec. 6.

IX. INSTRUCTIONS FOR SUBMITTAL

All submittals in response to this Registration Standard must be sent to the following address:

Document Processing Desk (RS-0017)
Office of Pesticide Programs - H7504C
U. S. Environmental Protection Agency
401 M St., SW
Washington, D.C. 20460

A. Manufacturing Use Products (MUPs) containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit for each product subject to this Registration Standard:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the "FIFRA Section 3(c)(2)(B) Summary Sheet" (EPA Form 8580-1), with appropriate attachments.

b. Confidential Statement of Formula (EPA Form 8570-4).

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months from receipt of this document you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

c. Product Specific Data Report (EPA Form 8580-4).

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table B, you must submit all product specific data.

B. Manufacturing Use Products containing the subject pesticide in combination with other active ingredients.

1. Within 90 days from receipt of this document, you must submit:

a. Generic Data Exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA sec. 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

b. Confidential Statement of Formula (EPA Form 8570-4)

c. Evidence of compliance with data compensation requirements of FIFRA sec. 3(c)(1)(D). Refer to 40 CFR 152.80-152.99.

2. Within 9 months of receipt of this document, you must submit:

a. Application for Pesticide Registration (EPA Form 8570-1).

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

c. Product Specific Data Report (EPA Form 8580-4).

3. Within the time frames set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the time frames set forth in Table B, you must submit all product specific data.

C. End Use Products containing the subject pesticide as sole active ingredient.

1. Within 90 days from receipt of this document, you must submit:

   a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

   b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from receipt of this document you must submit:

   a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

   b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

D. End Use Products containing the subject active ingredient as one of multiple active ingredients

1. Within 90 days from receipt of this document, you must submit:

   a. Generic data exemption Statement (EPA Form 8580-3), if applicable, or the FIFRA Section 3(c)(2)(B) Summary Sheet, with appropriate attachments (EPA Form 8580-1).

   b. Confidential Statement of Formula (EPA Form 8570-4).

2. Within 9 months from the receipt of this document, you must submit:

a. Product Specific Data Report (EPA Form 8580-4), if Table C lists required product-specific data.

b. Five copies of draft labeling, including the container label and any associated supplemental labeling.

3. Within the times set forth in Table A, you must submit all generic data, unless you are eligible for the generic data exemption. If for any reason any test is delayed or aborted so that the schedule cannot be met, immediately notify the Agency of the problem, the reasons for the problem, and your proposed course of action.

4. Within the times set forth in Table C, you must submit all product specific data.

E. Intrastate Products

Applications for full Federal registration of intrastate products were required to be submitted no later than July 31, 1988. Unless an application for registration was submitted by that date, no product may be released for shipment by the producer after July 31, 1988.

I. DATA APPENDICES

GUIDE TO TABLES

Tables A, B, and C contain listings of data requirements for the pesticides covered by this Registration Standard.

Table A contains generic data requirements that apply to the pesticide in all products, including data requirements for which a "typical formulation" is the test substance.

Table B contains product-specific data requirements that apply only to a manufacturing use product.

Table C contains product-specific data requirements that apply only to an end use product.

The data tables are generally organized according to the following format:

1. Data Requirement (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. The reference numbers accompanying each test refer to the test protocols set out in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Prot Royal Road, Springfield, VA 22161.

2. Test Substance (Column 2). This column lists the composition of the test substance required to be used for the test, as follows:

TGAI = Technical grade of the active ingredient
PAI = Pure active ingredient
PAIRA = Pure Active ingredient, radio labeled
TEP = Typical end use formulation
MP = Manufacturing use product
EP = End use product

Any other test substances, such as metabolites, will be specifically named in Column 2 or in footnotes to the table.

3. Use pattern (Column 3). This column indicates the use patterns to which the data requirement applies. Use patterns are the same as those given in 40 CFR Part 158. The following letter designations are used for the given use patterns:

A = Terrestrial, food
B = Terrestrial, non-food
C = Aquatic, food
D = Aquatic, non-food
E = Greenhouse, food

F = Greenhouse, non-food
G = Forestry
H = Domestic outdoor
I = Indoor

Any other designations will be defined in a footnote to the table.

4. Does EPA have data? (Column 4). This column indicates one of three answers:

YES - EPA has data in its files that completely satisfy this data requirement. These data may be cited by other registrants in accordance with data compensation requirements of Part 152, Subpart E.

PARTIALLY - EPA has some data in its files, but such data do not fully satisfy the data requirement. In some cases, the Agency may possess data on one of two required species or may possess data on one test substance but not all. The term may also indicate that the data available to EPA are incomplete. In this case, when the data are clarified, or additional details of the testing submitted by the original data submitter, the data may be determined to be acceptable. If this is the case, a footnote to the table will usually say so.

NO - EPA either possesses no data which are sufficient to fulfill the data requirement, or the data which EPA does possess are flawed scientifically in a manner that cannot be remedied by clarification or additional information.

5. Bibliographic citation (Column 5). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a GS number if no MRID number has been assigned. Refer to the Bibliography Appendices for a complete citation of the study.

6. Must additional data be submitted? (Column 6). This column indicates whether the data must be submitted to the Agency. If column 3 indicates that the Agency already has data, this column will usually indicate NO. If column e indicates that the Agency has only partial data or no data, this column will usually indicate YES. In some cases, even though the Agency does not

have the data, EPA will not require its submission because of the unique characteristics of the chemical; because data on another chemical can be used to fulfill the data requirement; or because the data requirement has been waived or reserved. Any such unusual situations will be explained in a footnote to the table.

7. Timeframe for submission (Column 7). If column t requires that data be submitted, this column indicates when the data are to be submitted, based on the issuance date of the Registration Standard. The timeframes are generally those established either as a result of a previous Data Call-In letter, or standardized timeframes established by PR Notice 85-5 (August 22, 1985).

8. Footnotes (at the end of each table). Self-explanatory.

Table A
Generic Data Requirements for MCPA

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.155 - 190 - Product Chemistry Analysis and Certification of Product Ingredients					
Product Identity and Composition					
61-2 - Description of Beginning Materials and Manufacturing Process	TGAI	No	00126755,00154066, 00154075,00154063, 00155233,00155743, 00158077,00159470	Yes[1]	1 Year
61-3 - Discussion of Formation of Impurities	TGAI	No	00159470,00154075, 00154063,00154066, 00126755,00158077, 00155233	Yes[2]	1 Year

Table A
Generic Data Requirements for MCPA

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.155 - 190 - Product Chemistry (cont'd)					
62-1 - Preliminary Analysis of Product Samples	TGAI	No	00159470,00154076, 00154064,40513001, 00126755,00158078, 00155743,00155234, 40077101,00079473, 00094623,00059949, 40169502,40171902, 40171802,40314302, 40314402,00105215, 40212901,40282501, 40306102,40306502, 40169501,40271501	Yes[3]	1 Year
Physical and Chemical Characteristics					
63-2 - Color	TGAI/PAI	No	00155099,00152836, 00159470	Yes[4]	1 Year
63-2 - Physical State	TGAI/PAI	No	00155099,00155743, 00159470,00152836	Yes[4]	1 Year
63-4 - Odor	TGAI/PAI	No	00155099,00155743, 00159470,00152836	Yes[4]	1 Year
63-5 - Melting Point	TGAI/PAI	No	00155099,00155743, 00159470,00152836	Yes[4,5]	1 Year
63-6 - Boiling Point	TGAI/PAI	No	00155743	Yes[4,6]	1 Year
63-7 - Density, Bulk Density or Specific Gravity	TGAI	No	00155099,00155743, 00159470,00152836, 00154067	Yes[4]	1 Year

Table A
Generic Data Requirements for MCPA

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
Physical and Chemical Characteristics (cont'd)					
63-8 - Solubility	TGAI or PAI	No	00155099,00155743, 00159470,40470101, 40471802,00152836	Yes[4]	1 Year
63-9 - Vapor Pressure	TGAI or PAI	No	00155099,00155743, 00159470,40471803, 00152836,00126755	Yes[4]	1 Year
63-10 - Dissociation Constant	TGAI or PAI	No	00159470,40471801, 00155743	Yes[4]	1 Year
63-11 - Octanol/Water Partitioning Coefficient	PAI	No	00159470,00152836, 00154067,00126755	Yes[4]	1 Year
63-12 - pH	TGAI	No	00155099,00155743, 00159470,00152836	Yes[4,7]	1 Year
63-13 - Stability	TGAI	No	00155743,00152836	Yes[4]	1 Year
Other Requirements:					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

158.155 - 190 - Product Chemistry - Footnotes - All numbers in parentheses refer to EPA registration numbers.

[1] Complete information must be provided regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the equipment used, reaction conditions, the chemical equations for each intended reaction (including a flow chart), the duration of each step of the process, purification procedures, and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning

Table A

Generic Data Requirements for MCPA

158.155 - 190 - Product Chemistry - Footnotes

material used in the manufacture of each product must be provided, along with information regarding the properties of those materials. This information is required for all manufacturing-use products (EPA Registration Numbers presented parenthetically) except the Riverdale 94 percent T acid (228-200) and 91 percent T isooctyl ester (228-198) and the BASF 85 percent T acid alternate formulation (7969-34). These requirements may be satisfied for the following products for which selected information is required: (i) The nature of the process, and the relative amounts of beginning material used are required for the Dow 93.3 percent Ts (464-585 and 464-595). (ii) The relative amounts of beginning materials, the name and quality control measures are required for the Dow 94 percent T (464-580). (iii) Data must be submitted regarding the nature of the process, the duration of each step, chemical equations of intended reaction, quality control measures, and the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture, for the Gilmore 94 and 95 percent Ts (42545-24 and 42545-9, respectively). (iv). The properties of the beginning materials are required for the 94 percent T (42545-24). (v) The nature of the process, the relative amounts of beginning materials, chemical equations, the duration of each intended reaction, equipment used, quality control measures, and the name and addresses of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product, along with information regarding the properties of those materials for the Kemisk Vaerk Kogen A/S 92 percent T (11636-3). (vi) The nature of the process, the relative amount of beginning materials, and quality control procedures for the A.H. Marks 93 percent and 94 percent Ts (15440-7 and 15440-9, respectively) and the duration of each step and the names and addresses of manufacturers, producers, or suppliers of the beginning material for the 94 percent T isooctyl ester (15440-9). (vii) Rhone-Poulenc and A.H. Marks must specify which technical product is manufactured by the submitted processes, and information must be provided regarding the nature of the process, the relative amounts of beginning materials and the order in which they are added, equipment used, reaction conditions, and duration of each step of the process for the Rhone-Poulenc product, and the nature of the process, relative amounts of beginning materials, the duration of each step, and quality control measures, and the names and addresses of manufacturers, producers, or suppliers of the beginning materials for the A.H. Marks product. These data requirements do not apply to the following products (228-200, the alternate formulation of 7969-34, and 228-198).

[2] A detailed discussion of all impurities that are or may be present at ≥ 0.1 percent, based on knowledge of the beginning materials, chemical reactions (intended and side) in the manufacturing process, and any contamination during and after production, including the formation of dibenzo-p-dioxins and dibenzofurans, must be submitted for all manufacturing-use products except the Riverdale 94 percent T acid (228-200) and 91 percent isooctyl ester (228-198) and the BASF 85 percent T acid alternate formulation (7969-34). These requirements may be satisfied for the following products by a discussion of the formation of selected impurities: the Gilmore 95 percent T acid (42545-9); the Dow T acid (464-580); the Dow 93.3 percent T isooctyl ester and butoxyethyl ester (EPA Registration Nos. 464-585 and 464-595, respectively); the unspecified Rhone-Poulenc T acid; and the Gilmore 94 percent isooctyl ester (42545-24).

[3] Preliminary analysis must be performed on five representative samples of all manufacturing-use products except the Riverdale 94 percent T acid (228-200) and 91 percent T isooctyl ester (228-198) and the BASF 93.6 percent T acid alternate formulation (7969-34) using fully validated analytical methods. Data must be provided for the active ingredient

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plus all impurities present at > 0.1 percent or of toxicological significance, including dibenzo-p-dioxins and dibenzofurans. These requirements may be satisfied for the following products by submission of certain data. Rhone-Poulenc must identify the T acid product for which data are available and submit these data for the remaining registered T acid product; in addition, validation studies and data depicting dibenzo-p-dioxins and dibenzofurans are required for both T acids. Dow must specify the number of batches of T acid (464-580) and T isooctyl ester (464-585) analyzed, validation studies (active ingredient and impurities), and data depicting dibenzo-p-dioxins and dibenzofurans for both products. Dow must also submit data regarding the impurities in the T isooctyl ester (464-585). Kemisk must define impurities abbreviated on the CSF for the T acid (11636-2) and submit information regarding the number of batches analyzed and data depicting dibenzofurans and validation studies for this product. A.H. Marks must identify the T acid product for which data are available and submit these data for the remaining registered T acid product; in addition, validation studies and data depicting dibenzo-p-dioxins and dibenzofurans are required for both T acids. Gilmore must submit data for additional impurities including dibenzofurans, identify the unknown, specify the number of batches analyzed, and submit validation data for the T acid (42545-9). Gilmore must also submit data for additional impurities including dibenzo-p-dioxins and dibenzofurans in five batches and submit validation data for the T isooctyl ester (42545-24).

[4] Data regarding physicochemical characteristics (color, physical state, odor, melting point, boiling point, specific gravity, solubility, vapor pressure, dissociation constant, partition coefficient, pH, and stability) as required in 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, Reference Nos. 63-2 to 63-13, must be submitted for technical products except the Riverdale 94 percent T acid (228-200) and the 91 percent T isooctyl ester (228-198) and the BASF 85 percent T acid alternate formulation (7969-34). The requirements may be satisfied for the following products by submission of data for selected properties: color, physical state, and odor (359-737, 7969-34, 11636-2, 11636-3, 42545-9); melting point (7969-34, 11636-2, 42545-9); boiling point (359-737, 11636-3); and density (359-737, 464-580, 464-582, 464-595, 7969-34, 11636-2, 11636-3, 15440-8, 15440-9, 42545-9, 42545-24). See Table B for additional requirements for data on physicochemical characteristics of technical products that are also manufacturing-use products.

[5] Data on melting point are required if the technical chemical is a solid at room temperature.

[6] Data on boiling point are required if the technical product is a liquid at room temperature.

[7] Data on pH are required if the test substance can be diluted or dispersed in water.

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Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.240 Residue Chemistry					
171-2 - Chemical Identity[1]		(See Index)			
171-3 - Directions for use					
171-4 - Nature of the residue (Metabolism) - Plants	PAIRA	Partially	00005575,00041633, 00053734,00053755	Yes[2]	2 Years
171-4 - Nature of the residue (Metabolism) - Livestock	PAIRA and plant metabolites	Partially	00004624,00004625, 00053734,00053755, 00027042	Yes[3,4]	2 Years
171-4 - Residue analytical methods	TGAI and metabolites	Partially	00004439,00004449, 00004453,00004491, 00004492,00004493, 00004627,00004632, 00004724,00004766, 00004787,00004822, 00004993,00005575, 00102704	Yes[5]	2 Years
171-4 - Storage stability	TEP and metabolites	No		Yes[6,7]	2 Years

Table A
Generic Data Requirements for MCPA

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.240 Residue Chemistry - (cont'd)					
171-4 - Magnitude of the residue in plants[8]					
Legume Vegetables					
- Beans	TEP	Partially	00004453	Yes[9,10]	2 Years
- Peas	TEP	Partially	00004443,00004773	Yes[11,12]	2 Years
Foliage of Legume Vegetables					
- Pea vines and hay	TEP	Yes	00004443	No	
Cereal Grains					
- Barley	TEP	Partially	00004613,00005567 00078931	Yes[13,14]	2 Years
- Oats	TEP	Partially	00023687	Yes[15,16]	2 Years
- Rice	TEP	Partially	00004764,00102704	Yes[17,18,19]	2 Years
- Rye	TEP	No		Yes[20,21]	2 Years
- Sorghum	TEP	Partially	00004993	Yes[22,23]	2 Years
- Wheat	TEP	Partially	00004651,00004655 00004659,00025394 00005575	Yes[24,25,26]	2 Years

Table A
Generic Data Requirements for MCPA

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.240 Residue Chemistry - Continued					
Forage. Fodder, and Straw of Cereal Grains					
- Barley forage and straw	TEP	Partially	00004613,00005567	Yes[27]	2 Years
- Oat forage and straw	TEP	Partially	00023687	Yes[28]	2 Years
- Rice straw	TEP	Partially	00004764	Yes[29,30]	2 Years
- Rye forage and straw	TEP	No	00004993	Yes[31]	2 Years
Sorghum forage and fodder	TEP	Partially	00004993	Yes[32]	2 Years
- Wheat straw	TEP	Partially	00004651,00004659, 00025394,00005575	Yes[33,34,35]	2 Years
Grass Forage and Hay					
- Canary grass	TEP	Yes	00084292	Yes[36,37,]	2 Years
- Pasture and rangeland grass	TEP	Partially	00004449	Yes[38]	2 Years
Nongrass animal feeds					
- Alfalfa forage and hay	TEP	No		Yes[39]	2 Years
- Clover forage and hay	TEP			Yes[40]	2 Years
- Lespedeza forage and hay	TEP	No		Yes[41]	2 Years

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Generic Data Requirements for MCPA

Data Requirement		Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.240 Residue Chemistry - (cont'd)						
	- Trefoil forage and hay	TEP	No		Yes[42]	2 Years
	- Vetch forage and hay	TEP	No		Yes[43]	2 Years
	Miscellaneous Commodities - Flax	TEP	No		Yes[44,45]	2 Years
171-4	Magnitude of residue in Meat/Milk/Poultry/Eggs	TGAI or metabolites	Partially	00004625,00004626	Reserved[46]	

158.240 Footnotes

[1] The same chemical identity data are required as under 158.120, with emphasis on impurities that could constitute residue problems. Refer to Product Chemistry Data Requirements tables.

[2] Data depicting the distribution and metabolism of ring-labeled [14]MCPA in or on the grain and straw of wheat. A completely characterized test substance representative of technical MCPA (including impurities) used in commercial formulations must be applied postemergence at rates sufficiently high to permit characterization of ^{14}C-residues. The identities and quantities of residues in or on mature plant parts must be determined in order to elucidate terminal residues. Representative samples must also be analyzed by proposed enforcement methods to ascertain that all residues of concern are determined.

[3] Metabolism studies utilizing ruminants and poultry. Animals must be dosed orally for a minimum of 3 days with uniformly ring-labeled [14]MCPA at a level sufficient to make residue identification and quantification possible. Milk and eggs must be collected twice a day during the dosing period. Animals must be sacrificed within 24 hours of the final dose. The distribution and identity of residues must be determined in milk, eggs, liver, kidney, muscle, and fat. Samples from these studies must also be analyzed using proposed enforcement methods to ascertain that the methods are capable of adequately recovering and identifying all residues of toxicological concern.

Table A
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158.240 Footnotes - (cont'd)

[4] Data depicting the nature of MCPA residues in swine are also required if the required metabolism studies with ruminants and poultry reveal that the metabolism of MCPA in these animals differs from that in rats.

[5] Representative plant samples, ruminant tissues and milk bearing residues of MCPA must be subjected to analysis by multiresidue protocols I, II, III, and IV in PAM Vol. I. These protocols are available from the National Technical Information Service (NTIS) under Order No. PB203734/AS.

[6] Samples bearing field weathered residues or fortified samples of one representative commodity from each crop group and representative animal commodities (meat, milk, eggs) must be analyzed immediately after harvest or fortification and again after storage intervals that are equivalent to those reflected in all previously submitted and currently requested data. Storage conditions for the samples must also reflect those in previously submitted and currently requested data. The chosen intervals must also allow for unforeseen delays in sample storage. In laboratory tests using fortified samples, the pure active ingredient and pure metabolites (if necessary) must be used. However, if field weathered samples are used, the test substance must be a typical end-use product. For additional guidance on conducting storage stability studies, the registrant is referred to an August 1987 Position Document on the Effects of Storage on the Validity of Pesticide Residue Data available from NTIS under order No. PB88112362/AS.

[7] Information on the intervals and conditions of storage must be submitted for the samples of sorghum grain and sorghum forage reported in MRID No. 00004493.

[8] If it is determined that the data on nitrosamines and the data requested on dioxins in end-use products indicate that these impurities may occur in or on food items at toxicologically significant levels, data depicting the levels of these impurities in or on raw agricultural and processed commodities may be required.

[9] Data depicting residues of MCPA in or on dried beans harvested following application of the 4 lb/gal EC of the formulation diethylamine salt of MCPA at 1.5 lb ae/A, made when the plants are 6 inches tall. The tests must be conducted in CA. The registrant must amend all pertinent labels to specify a PHI based on the minimum interval expected between application at the 6-inch stage and harvest. Adequate residue data must be available reflecting harvest at the proposed interval. Alternatively, the registrant may elect to cancel this use permitted under EPA SLN No. CA-760142.

[10] Use directions must be proposed and appropriate supporting residue data submitted for the raw agricultural commodities bean vines and bean hay. Alternatively, the registrant may amend all pertinent product labels to impose a restriction of the feeding of these commodities to livestock.

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Generic Data Requirements for MCPA

158.240 Footnotes - (cont'd)

[11] Data depicting residues of MCPA in or on peas (succulent and dry) harvested after application of representative EC and SC/L formulations of the diethylamine salt of MCPA at 0.37 lb ae/A, each formulation applied in separate tests. Applications are to be made when the plants are 8 inches tall. Aerial and ground applications must be made in 15 gal/A. The tests must be conducted in WI (28%) or MN (22%), WA (17%), OR (7%), and in DE (3%), States that collectively accounted for ca. 80 percent of 1985 U.S. pea production and represent the major U.S. growing regions (Agricultural Statistics, 1986, page 162). The registrant must propose a PHI based on the minimum interval expected between application to 8-inch plants and harvest.

[12] Data depicting residues of MCPA in or on peas (succulent and dry) harvested after application of the 1.86 lb/gal EC and 2 lb/gal SC/L formulations of the sodium salt of MCPA at 0.37 lb ae/A, each formulation applied in separate tests using aerial equipment. Applications are to be made when the plants are 3 inches tall. The tests must be conducted in WI (28%) or MN (22%), WA (17%) or OR (7%), and in DE (3%), States that collectively accounted for ca. 80 percent of 1985 U.S. pea production and represent the major U.S. growing regions. The registrant must propose a PHI based on the minimum interval expected between application to 3-inch plants and harvest.

[13] Residue data required for wheat will be translated to barley.

[14] Processing data required for wheat will be translated to barley.

[15] Residue data required for wheat will be translated to oats.

[16] Processing data required for wheat will be translated to oats.

[17] Data depicting residues of MCPA in or on rice grain harvested following postemergence application of the 2 lb/gal SC/L formulation of the sodium salt and representative EC formulations of the sodium salt and butoxyethyl ester forms of MCPA at 1.25 lb ae/A applied with ground equipment, each formulation in a separate test. Also, data are required depicting residues of MCPA in or on rice grain harvested following postemergence application of representative EC and SC/L formulations of the diethylamine salt of MCPA at 1.4 lb ae/A, applied with aerial equipment in 3 gal/A and with ground equipment in 8 gal/A in separate tests. Tests with the sodium salt must be conducted in CA where this use in permitted. The tests using the other formulations must be conducted in AR (40%), LA (15%), or TX (13%) and in CA (22%), which collectively account for ca. 90 percent of the 1985 U.S. rice production (Agricultural Statistics, 1986, page 21). The registrant may satisfy some of these data requirements by providing additional information on the tests described in MRID Nos. 00004764 and 00102704.

[18] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the latest permitted postemergence application and harvest. The data submitted to support the established tolerance must reflect these proposed restrictions.

158.240 Footnotes - (cont'd)

[19] Data depicting the potential for concentration of residues in hulls, bran, polished rice, and grain dust processed from rice grain bearing measurable weathered residues. If the data indicate a potential for concentration of residues in any of these processed commodities, an appropriate food or feed additive tolerance must be proposed.

[20] Residue data required for wheat will be translated to rye.

[21] Processing data required for wheat will be translated to rye.

[22] Data depicting the potential for concentration of residues in flour, starch, and grain dust from sorghum grain bearing measurable weathered residues. If the data indicate a potential for concentration of residues in any of these commodities during processing, an appropriate food or feed additive tolerance must be proposed.

[23] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the latest permitted postemergence application and harvest. The data submitted to support the established tolerance must reflect these proposed restrictions.

[24] Data depicting residues of MCPA in or on wheat grain harvested following application, made at the boot stage, of each of the following formulations in separate tests: (i) the 1.86 lb/gal EC formulation of the sodium salt at 1.5 lb ae/A; (ii) the 2 lb/gal SC/L formulation of the sodium salt at 1.5 lb ae/A; (iii) representative EC and SC/L formulations of the diethylamine salt at 1.4 lb ae/A; and (iv) a representative EC formulation of the isooctyl ester at 1.5 lb ae/A. Each formulation must be applied using aerial and ground equipment. The tests must be conducted in KS (18%) or NE (4%), ND (13%), and OK (7%) or TX (8%), States that accounted for ca. 60 percent of the 1985 total U.S. wheat production and represent the major domestic wheat growing regions (Agricultural Statistics, 1986, page 6).

[25] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the minimum interval expected between the boot stage and harvest. The data submitted to support the established tolerance must reflect these proposed restrictions.

[26] Data depicting the potential for concentration of residues in flour, bran, middlings, shorts, and grain dust from wheat grain bearing measurable weathered residues. If the data indicate a potential for concentration of residues in any of these commodities during processing, an appropriate food or feed additive tolerance must be proposed.

[27] Residue data required for wheat will be translated to barley.

[28] Residue data required for wheat will be translated to oats.

[29] Data depicting residues of MCPA in or on rice straw harvested following postemergence application of representative EC and SC/L formulations of the sodium salt and butoxyethyl ester forms of MCPA at 1.25 lb ae/A applied with ground equipment, each formulation in a separate test. Also, data are required depicting residues of MCPA in or on rice straw harvested following postemergence application of representative EC and SC/L formulations of the diethylamine salt of MCPA at 1.4 lb ae/A, applied with aerial equipment in 3 gal/A and with ground equipment in 8 gal/A in separate tests. The sodium salt must be conducted in CA. The tests using the other formulations must be conducted in AR (40%), LA (15%) or TX (13%), and in CA (22%), which collectively accounted for ca. 90 percent of the 1985 U.S. rice production (Agricultural Statistics, 1986, page 21). The registrant may satisfy some of these data requirements by providing additional information on the tests described in MRID Nos. 00004764 and 00102704.

158.240 Footnotes - (cont'd)

[30] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the latest permitted postemergence application and harvest. The data submitted to support the established tolerance must reflect these proposed restrictions.

[31] Residue data required for wheat will be translated to rye.

[32] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the latest permitted postemergence application and harvest. The data submitted to support the established tolerance must reflect these proposed restrictions.

[33] Data depicting residues of MCPA in or on wheat straw harvested following application, made at the boot stage, of each of the following formulations in separate tests: (i) a representative EC formulation of the sodium salt at 1.5 ae/A; (ii) a representative SC/L formulation of the sodium salt at 1.5 lb ae/A; (iii) representative EC and SC/L formulations of the diethylamine salt at 1.4 lb ae/A; and (iv) a representative EC formulation of the isooctyl ester at 1.5 lb ae/A. Each formulation must be applied using aerial and ground equipment. The tests must be conducted in KS (18%) or NE (4%), ND (13%) and OK (7%) or TX (8%), States that accounted for ca. 60 percent of the 1985 total U.S. wheat production and represent the major domestic wheat growing regions (Agricultural Statistics, 1986, page 6).

[34] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the minimum interval expected between the boot stage and harvest. The data submitted to support the established tolerance must reflect these proposed restrictions.

[35] Tolerances must be proposed and appropriate supporting residue data submitted for wheat forage and hay. Alternatively, the registrant may amend all labels to bear feeding and grazing restrictions.

[36] The registrant must amend all pertinent product labels to specify a maximum number of applications per season and a PHI based on the latest permitted postemergence application and harvest. A pregrazing interval must be proposed also. The data submitted to support the established tolerances must reflect these proposed restrictions.

[37] A tolerance must be proposed and appropriate supporting residue data submitted for the raw agricultural commodity canary grass forage.

[38] Data depicting residues of MCPA in or on pasture grass forage and hay harvested 7 and 21 days, respectively, following the last of two applications of representative EC and SC/L formulations of the sodium salt and an EC formulation of the isooctyl ester of MCPA at 1.5 lb ae/A and representative EC and SC/L formulations of the diethylamine salt at 2 lb ae/A. Also, data are required depicting residues of MCPA in or on rangeland grass forage collected on the day of the final treatment. Each formulation must be applied in the spring and in the fall using ground and aerial equipment in separate tests. Tests on pasture grasses must be conducted in KY (6%) or TN (4%), MO (11%) and representative of KS (4%), and AR (3%), NY (4%) or PA (4%), and TX (13%) and representative of SD (12%), OK (5%), and representative of KS (8%) and OR (4%), States that collectively

Table A
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158.240 Footnotes - (cont'd)

accounted for ca. 50 percent and ca. 60 percent, respectively, of pasture and rangeland grass production (1982 Census Agriculture, Vol. 1, Part 51, pages 330-331). The registrant must propose a PHI for application of the sodium salt formulations; the available data indicate that a PHI of 21 days would be appropriate. "Preslaughter" intervals must be deleted from all pertinent labels.

[39] Data depicting residues of MCPA in or on alfalfa and alfalfa hay harvested 7 days following application of representative EC and SC/L formulations of the sodium salt and diethylamine salt forms of MCPA at 0.5 lb ae/A and a representative SC/L formulation of the diethanolamine salt at 0.7 lb ae/A using ground and aerial equipment. The registrant must propose a PHI based on the minimum interval expected between the latest permitted postemergence application and harvest. A pregrazing interval and a PHI must be proposed for application of the diethylamine and diethanolamine salt forms. A PHI must be proposed for application of the sodium salt formulations. The data submitted to support the established tolerances must reflect these proposed restrictions. The tests must be conducted in CA (7%), ID (5%), IA (7%), and representative of NE (4%), and SD (6%), MI (4%), and MN (7%) or WI (12%), States that collectively accounted for ca. 50 percent of U.S. alfalfa production and represent the major U.S. alfalfa growing region (1982 Census of Agriculture, Vol. 1, Part 51, page 328).

[40] Residue data required for alfalfa will be translated to clover.

[41] Residue data required for alfalfa will be translated to lespedeza.

[42] Residue data required for alfalfa will be translated to trefoil.

[43] Residue data required for alfalfa will be translated to vetch.

[44] Data depicting residues of MCPA in or on flaxseed and flax straw harvested following application of representative EC and SC/L formulations of the sodium salt of MCPA at 1 lb ae/A, the diethylamine salt of MCPA at 0.5 lb ae/A, the diethanolamine salt at 0.37 lb ae/A, and the isooctyl or butoxyethyl ester at 0.25 lb ae/A. Each formulation must be applied using ground and aerial equipment. The tests must be conducted in MN, ND, or SD, States that collectively accounted for 100 percent of the 1985 U.S. flax production (Agricultural Statistics, 1986, page 115). The registrant must propose a PHI and pregrazing interval and all data submitted in support of the established tolerances must reflect these restrictions.

[45] Data depicting the potential for concentration of residues in oil and meal processed from flaxseed bearing measurable weathered residues. If the data indicate a potential for concentration of residues in either of these commodities, an appropriate food or feed additive tolerance must be proposed.

[46] Numerous data gaps exist pertaining to the data requirements on livestock feed items; therefore, a maximum theoretical dietary intake of MCPA by livestock cannot be estimated. In addition, the metabolism of MCPA in animals is not adequately understood. Upon receipt of the data requested on animal metabolism and residues in or on feed items, the adequacy of the established tolerances for residues in animal commodities will be assessed.

Table A
Generic Data Requirements for MCPA Acid/Sodium Salt

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.340 - Toxicology						
ACUTE TESTING						
81-1 - Acute Oral - Rat	TGAI	A,B	Yes	00021972	No	
81-2 - Acute Dermal - Rat	TGAI	A,B	Yes	00144735	No	
81-3 - Acute Inhalation - Rat	TGAI	A,B	Yes	40053101	No	
81-4 - Eye Irritation - Rabbit	TGAI	A,B	Yes	00021974	No	
81-5 - Dermal Irritation - Rabbit	TGAI	A,B	No		Yes	1 Year
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B	No		Yes	1 Year
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A	No		No[1]	

Table A
Generic Data Requirements for MCPA Acid/Sodium Salt

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.340 - Toxicology (cont'd)						
SUBCHRONIC TESTING						
82-1 - 90-Day Feeding - Rodent	TGAI	A,B	Yes	00165471	No	
- Nonrodent	TGAI	A,B	Yes	00152867	No	
82-2 - 21-Day Dermal	TGAI	A,B	No		Yes	2 Years
82-3 - 90-Day Dermal	TGAI	A,B	No		No[2]	
82-4 - 90-Day Inhalation Rat	TGAI	A,B	No		No[2]	
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No		No[3]	
CHRONIC TESTING						
83-1 - Chronic Toxicity - - Rodent	TGAI	A,B	Yes	40634101	No	
- Nonrodent	TGAI	A,B	Yes	00164352	No	
83-2 - Oncogenicity - Rat	TGAI	A,B	Yes	40634101	No	
- Mouse	TGAI	A,B	Yes	40792301	No	

Table A
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Data Requirement	Test Substance	Use Patterns	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.340 - Toxicology (cont'd)						
CHRONIC TESTING						
83-3 - Teratogenicity - Rat	TGAI	A,B	No		Yes[4]	2 Years
- Rabbit	TGAI	A,B	No		Yes[4]	2 Years
83-4 - Reproduction - 2-Generation	TGAI	A,B	Yes	40041701	No	
84-2 - Gene Mutation	TGAI	A,B	No		Yes	1 Year
84-2 - Chromosomal Aberration	TGAI	A,B	Yes	40027501	No	
84-2 - Other Mechanisms of Mutagenicity	TGAI	A,B	Yes	00148720	No	
85-1 - General Metabolism	PAI or PAIRA	A,B	Yes	00041634	No	
Special Neurotoxicity Testing	TGAI	A,B	No		Yes[5]	1 Year

§158.340 - Toxicology - Footnotes

[1] This test is not required since MCPA does not have a chemical structure similar to organophosphates.
[2] This study is not required to support the registered use patterns.
[3] Since an acute neurotoxicity study is not required, this study is not presently required.

Table A
Generic Data Requirements for MCPA Acid/Sodium Salt

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§158.340 - Toxicology (cont'd)

[4] Originally not required in the 1982 Registration Standard based upon data evaluated at that time; Agency reevaluation of the teratology data has concluded that the studies are not adequate to fill the data requirements.

[5] A protocol must be submitted and approved by the Agency prior to submission of this study. For such studies the following must be addressed. 1)An experimental animal species must be chosen that has been shown to respond to a "chemical known to produce sensory paresthesiaes like those seen most often in the case reports." 2)Parameters observed must have been shown to detect the effects, in experimental animals, of a known neurotoxin having this type of effect in man. 3)The dose tested must be a single large dermal dose, in the order of an LD_{10}, which produces obvious signs of toxicity. The dose may be applied to the skin of the back and the test animals observed for at least 30 days after dosing. 4)The compound tested should be MCPA acid or the sodium salt and each of the organic amine salts and organic esters.

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.340 - Toxicology						
ACUTE TESTING:						
81-1 - Oral - Rat	TGAI	A,B	Partially	00160158,00156458	Yes	2 Years
81-2 - Dermal	TGAI	A,B	Partially	00156459,00160157	Yes	2 Years
81-3 - Inhalation - Rat	TGAI	A,B	Partially	00146317,40076201, 00156460	Yes	2 Years
81-4 - Eye Irritation - Rabbit	TGAI	A,B	Partially	00156456,00145865	Yes	1 Year
81-5 - Dermal Irritation - Rabbit Irritation	TGAI	A,B	Partially	00160160,40352001, 00156457	Yes	1 Year
81-6 - Dermal Sensitization - Guinea Pig	TGAI	A,B	Partially	40352101	Yes	1 Year
81-7 - Acute Delayed Neurotoxicity - Hen	TGAI	N/A	No		No[1]	
SUBCHRONIC TESTING:						
82-1 - 90-Day Feeding - Rodent	TGAI	A,B	No		Yes	2 Years
Nonrodent	TGAI	A,B	No		Yes	2 Years
82-2 - 21-Day Dermal	TGAI	A,B	No		Yes	2 Years

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.340 - Toxicology (cont'd)						
SUBCHRONIC TESTING: (cont'd)						
82-3 - 90-Day Dermal	TGAI	A,B	No		No^{2}	
82-4 - 90-Day Inhalation Rat	TGAI	A,B	No		No^{2}	
82-5 - 90-Day Neurotoxicity	TGAI	A,B	No		No^{3}	
CHRONIC TESTING:						
83-1 - Chronic Toxicity -						
- Rodent	TGAI	A,B	No		No^{4,5}	
- Nonrodent	TGAI	A,B	No		No^{4,5}	
83-2 - Oncogenicity						
- Rat	TGAI	A,B	No		No^{4,5}	
- Mouse	TGAI	A,B	No		No^{4,5}	
83-3 - Teratogenicity						
- Rat	TGAI	A,B	No		Yes	2 Years
- Rabbit	TGAI	A,B	No		Yes	2 Years
83-4 - Reproduction - 2-Generation	TGAI	A,B	No		No^{4,5}	

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
§158.340 - Toxicology (cont'd)						
MUTAGENICITY TESTING						
84-2 - Gene Mutation	TGAI	A,B	No		Yes	1 Year
84-2 - Chromosomal Aberration	TGAI	A,B	No		Yes	1 Year
84-4 - Other Mechanisms of Mutagenicity	TGAI	A,B	No		Yes	1 Year
SPECIAL TESTING						
85-1 - General Metabolism	PAI or PAIRA	A,B	No		Yes	2 Years
Special Neurotoxicity Study	TGAI	A,B	No		Yes[6]	1 Year

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[1] This test not required since MCPA does not have a chemical structure similar to organophosphates.

[2] This study is not required to support the registered use patterns.

[3] Since an acute neurotoxicity study is not required, this study is not presently required. Amines\esters of MCPA are not organophosphates.

[4] Required if measurable residues of the organic amines or ester moieties are present on the RACs or processed foods.

[5] Required if the acute toxicology studies required show significant differences in toxic effect(s) (change in toxicity category) compared with MCPA acid and/or its sodium salt.

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission

§158.340 - Toxicology footnotes (cont'd)

[6] A protocol must be submitted and approved by the Agency prior to submission of this study. For such studies the following must be addressed. 1)An experimental animal species must be chosen that has been shown to respond to a "chemical known to produce sensory paresthesiaes like those seen most often in the case reports." 2)Parameters observed must have been shown to detect the effects, in experimental animals, of a known neurotoxin having this type of effect in man. 3)The dose tested must be a single large dermal dose, in the order of an LD_{10}, which produces obvious signs of toxicity. The dose may be applied to the skin of the back and the test animals observed for at least 30 days after dosing. 4)The compound tested should be MCPA acid or the sodium salt and each of the organic amine salts and organic esters.

Table A
Generic Data Requirements for MCPA Acid

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 Hydrolysis	TGAI or PAIRA	ABC	No		Yes	1 Year
Photodegradation						
161-2 In Water	TGAI or PAIRA	ABCDG	No		Yes	1 Year
161-3 On Soil	TGAI or PAIRA	A	No		No	
161-4 In Air	TGAI or PAIRA	A	No		Reserved[1]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	ABG	No		Yes	2 Years
162-2 - Anaerobic Soil	TGAI or PAIRA	A	Yes		No[2]	2 Years
162-3 - Anaerobic Aquatic	TGAI or PAIRA	CD	Yes	40461901	No	
162-4 - Aerobic Aquatic	TGAI or PAIRA	CD	No		Yes	2 Years

Table A
Generic Data Requirements for MCPA Acid

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	ABCDG	Partially	00146192	Yes[3]	1 Year
163-2 - Volatility (Lab)	TEP	A	No		Reserved[1]	
163-3 - Volatility (Field)	TEP	A	No		Reserved[1]	
DISSIPATION STUDIES - FIELD:						
164-1 - Soil	TEP	AB	No		Yes	2 Years
164-2 - Aquatic (Sediment)	TEP	CD	No		No	
164-3 - Forestry	TEP	G	No		No	
164-4 - Combination and Tank Mixes	TEP	—	—		—	
164-5 - Soil, Long-Term	TEP	AC	No		Reserved[4]	

Table A
Generic Data Requirements for MCPA Acid

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate (cont'd)						
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		No	
165-2 - Rotational Crops (Field)	TEP	A	No		No	
165-3 - Irrigated Crops	TEP	CD	No		No	
165-4 - In Fish	TGAI or PAIRA	ABCDG	No		Yes	1 Year
165-5 In Aquatic Nontarget	TEP	DG	No		Reserved[5]	
158.390 - Reentry Protection						
132-1 - Foliar Dissipation	TEP	ABCDG	No		No[6]	
132-1 - Soil Dissipation	TEP	—	No		No[6]	
133-3 - Dermal Exposure	TEP	ABCDG	No		No[6]	
133-4 - Inhalation Exposure	TEP	ABCDG	No		No[6]	

Table A
Generic Data Requirements for MCPA Acid

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.440 Spray Drift						
202-1 Drift Field Evaluation	TEP	ABCDG	No		No[6]	
202-2 Droplet Size Spectrum	TEP	ABCDG	No		No[6]	

158.290 Environmental Fate; 158.390 Reentry Protection; 158.440 Spray Drift Footnotes

[1] The need for photodegradation in air and laboratory/field volatility studies will be reassessed upon evaluation of acceptable vapor pressure data for each chemical form of MCPA.

[2] Anaerobic soil data, for the MCPA acid only, is satisfied by acceptable data for the anaerobic aquatic metabolism study for the MCPA acid and sodium salt. Data for all other applicable MCPA organic salt and ester forms are required for the anaerobic aquatic metabolism study and may be substituted for the anaerobic soil metabolism study.

[3] Additional data on both aged and unaged test substances are required with special interest paid to the mobility of the degradates.

[4] May be required pending the receipt and review of data under 164-1 and 162-1.

[5] Reserved pending the receipt and review of data under 165-4.

[6] Does not exceed the toxicology criteria for data requirements. In the event that future toxicity concerns arise, this data requirement will be reassessed.

Table A
Generic Data Requirements for MCPA Sodium Salt and Amines

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 Hydrolysis	TGAI or PAIRA	ABCG	No		Yes[1]	1 Year
Photodegradation						
161-2 In Water	TGAI or PAIRA	ABCG	No		Yes[1]	1 Year
161-3 On Soil	TGAI or PAIRA	A	No		Yes[1]	1 Year
161-4 In Air	TGAI or PAIRA	A	No		Reserved[4]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	ABG	No		Yes[1]	2 Years
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes[1,5]	2 Years
162-3 - Anaerobic Aquatic	TGAI or PAIRA	CD	No		Yes[2,5]	2 Years
162-4 - Aerobic Aquatic	TGAI or PAIRA	CD	No		Yes[2,5]	2 Years

Table A
Generic Data Requirements for MCPA Sodium Salt and Amines

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	ABCDG	Partially	00146192	Yes[1,6]	1 Year
163-2 - Volatility (Lab)	TEP	A	No		Reserved[1,4]	
163-3 - Volatility (Field)	TEP	A	No		Reserved[1,4]	
DISSIPATION STUDIES - FIELD:						
164-1 - Soil	TEP	AB	No		Yes[1]	2 Years
164-2 - Aquatic (Sediment)	TEP	CD	No		Yes[2]	2 Years
164-3 - Forestry	TEP	G	No		Yes[3]	2 Years
164-4 - Combination and Tank Mixes	TEP	—	—		—	
164-5 - Soil, Long-Term	TEP	AC	No		Reserved[1,7]	

Table A
Generic Data Requirements for MCPA Sodium Salt and Amines

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate (cont'd)						
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[1]	2 Years
165-2 - Rotational Crops (Field)	TEP	A	No		Yes[1,8]	3 Years
165-3 - Irrigated Crops	TEP	C	No		Yes[2]	3 Years
165-4 - In Fish	TGAI or PAIRA	ABCG	No		Yes[1]	1 Year
165-5 In Aquatic Nontarget	TEP	G	No		Reserved[3,9]	
158.390 - Reentry Protection						
132-1 - Foliar Dissipation	TEP	ABCG	No		No[10]	
132-1 - Soil Dissipation	TEP	—	No		No[10]	
133-3 - Dermal Exposure	TEP	ABCG	No		No[10]	
133-4 - Inhalation Exposure	TEP	ABCG	No		No[10]	

Table A
Generic Data Requirements for MCPA Sodium Salt and Amines

Data Requirement	Test Substance	Use Pattern-	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.440 Spray Drift						
202-1 Drift Field Evaluation	TEP	ABCG	No		No[10]	
202-2 Droplet Size Spectrum	TEP	ABCG	No		No[10]	

158.290 Environmental Fate; 158.390 Reentry Protection; 158.440 Spray Drift Footnotes

[1] Data are required for the sodium salt, diethanolamine salt and the dimethylamine salt. Data on MCPA acid will satisfy requirements for the sodium salt of MCPA.

[2] Data are required for the sodium salt and the dimethylamine salt. Data on MCPA acid will satisfy the requirements for the sodium salt of MCPA.

[3] Data are required for the dimethylamine salt.

[4] The need for photodegradation in air and laboratory/field volatility studies will be reassessed upon evaluation of acceptable vapor pressure data for each chemical form of MCPA.

[5] Anaerobic soil data, for the MCPA acid only, is satisfied by acceptable data for the anaerobic aquatic metabolism study for the MCPA acid and sodium salt. Data for all other applicable MCPA amines are required for the anaerobic aquatic metabolism study and may be substituted for the anaerobic soil metabolism study.

[6] Additional data on both aged and unaged test substances are required with special interest paid to the mobility of the degradates.

[7] May be required pending the receipt and review of data under 164-1 and 162-1.

[8] Field rotational crop studies are reserved pending the results of an acceptable confined rotational crop study. No rotational crop interval has been set in this Standard due to data gaps. Once acceptable data are available, appropriate rotational crop intervals (if needed) will be established.

[9] Reserved pending the receipt and review of data under 165-4.

[10] Does not exceed the toxicology criteria for data requirements. In the event that future toxicity concerns arise, this data requirement will be reassessed.

Table A
Generic Data Requirements for MCPA Esters

Data Requirement	Test Substance	Use Pattern-	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate						
DEGRADATION STUDIES-LAB:						
161-1 Hydrolysis	TGAI or PAIRA	ABCDG	No		Yes[1]	1 Year
Photodegradation						
161-2 In Water	TGAI or PAIRA	ABCDG	No		Yes[1]	1 Year
161-3 On Soil	TGAI or PAIRA	A	No		Yes[1]	1 Year
161-4 In Air	TGAI or PAIRA	A	No		Reserved[3]	
METABOLISM STUDIES-LAB:						
162-1 - Aerobic Soil	TGAI or PAIRA	ABG	No		Yes[1]	2 Years
162-2 - Anaerobic Soil	TGAI or PAIRA	A	No		Yes[1,4]	2 Years
162-3 - Anaerobic Aquatic	TGAI or PAIRA	CD	No		Yes[1,4]	2 Years
162-4 - Aerobic Aquatic	TGAI or PAIRA	CD	No		Yes[1,4]	2 Years

Table A
Generic Data Requirements for MCPA Esters

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate						
MOBILITY STUDIES:						
163-1 - Leaching and Adsorption/ Desorption	TGAI or PAIRA	ABCDG	Partially	00146192	Yes^{1,5}	1 Year
163-2 - Volatility (Lab)	TEP	A	No		Reserved^{1,3}	
163-3 - Volatility (Field)	TEP	A	No		Reserved^{1,3}	
DISSIPATION STUDIES - FIELD:						
164-1 - Soil	TEP	AB	No		Yes^{1}	2 Years
164-2 - Aquatic (Sediment)	TEP	CD	No		Yes^{2}	2 Years
164-3 - Forestry	TEP	G	No		Yes^{1}	2 Years
164-4 - Combination and Tank Mixes	TEP	—	—		—	
164-5 - Soil, Long-Term	TEP	AC	No		Reserved^{1,6}	

Table A
Generic Data Requirements for MCPA Esters

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.290 Environmental Fate (cont'd)						
ACCUMULATION STUDIES:						
165-1 - Rotational Crops (Confined)	PAIRA	A	No		Yes[1]	2 Years
165-2 - Rotational Crops (Field)	TEP	A	No		Yes[1,7]	3 Years
165-3 - Irrigated Crops	TEP	CD	No		Yes[2]	3 Years
165-4 - In Fish	TGAI or PAIRA	ABCDG	No		Yes[1]	1 Years
165-5 In Aquatic Nontarget	TEP	DG	No		Reserved[1,8]	
158.390 - Reentry Protection						
132-1 - Foliar Dissipation	TEP	ABCDG	No		No[9]	
132-1 - Soil Dissipation	TEP	—	No		No[9]	
133-3 - Dermal Exposure	TEP	ABCDG	No		No[9]	
133-4 - Inhalation Exposure	TEP	ABCDG	No		No[9]	

Table A
Generic Data Requirements for MCPA Esters

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
158.440 Spray Drift						
202-1 Drift Field Evaluation	TEP	ABCDG	No		No[9]	
202-2 Droplet Size Spectrum	TEP	ABCDG	No		No[9]	

158.290 Environmental Fate; 158.390 Reentry Protection; 158.440 Spray Drift Footnotes

[1] Data are required for the butoxyethyl ester and the isooctyl ester derivatives.

[2] Data are required for the isooctyl ester.

[3] The need for photodegradation in air and laboratory/field volatility studies will be reassessed upon evaluation of acceptable vapor pressure data for each chemical form of MCPA.

[4] Anaerobic soil data, for the MCPA acid only, is satisfied by acceptable data for the anaerobic aquatic metabolism study for the MCPA acid and sodium salt. Data for all other applicable MCPA organic salt and ester forms are required for the anaerobic aquatic metabolism study and may be substituted for the anaerobic soil metabolism study.

[5] Additional data on both aged and unaged test substances are required with special interest paid to the mobility of the degradates.

[6] May be required pending the receipt and review of data under 164-1 and 162-1.

[7] Field rotational crop studies are reserved pending the results of an acceptable confined rotational crop study. No rotational crop interval has been set in this Standard due to data gaps. Once acceptable data are available, appropriate rotational crop intervals (if needed) will be established.

[8] Reserved pending the receipt and review of data under 165-4.

[9] Does not exceed the toxicology criteria for data requirements. In the event that future toxicity concerns arise, this data requirement will be reassessed.

Table A
MCPA Acid Generic Data Requirements

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.490 - Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	B	Yes	40019201	No	
71-2 - Avian Dietary LC_{50}						
a. Upland Game Bird	TGAI	B	Yes	00163844	No	
b. Waterfowl	TGAI	B	Yes	00163844	No	
71-3 - Wild Mammal Toxicity	TGAI	B	No		No	
71-4 - Avian Reproduction	TGAI	B	No		Yes	2 Years
71-5 - Simulated and Actual Testing for Birds and Mammals	TEP	B	No		Reserved[1]	

Table A
MCPA Acid Generic Data Requirements

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
§158.490 - Wildlife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}						
a. Coldwater	TGAI	B	Yes	00041294,00041295, 00029654	No	
	TEP	B	No		No[2]	
b. Warmwater	TGAI	B	Yes	00041294,00041295, 00029654	No	
	TEP	B	No		No[2]	
72-2 - Freshwater Aquatic Invertebrate LC_{50}	TGAI	B	Yes	00041294,00041295, 00029654	No	
	TEP	B	No		No[2]	
72-3 - Estuarine/Marine Organism LC_{50}	TGAI	B	Partially	40062002,40062003	Yes[6]	1 Year
	TEP	B	No		No[2]	
72-4 - Fish Early Life Stage/ Aquatic Invertebrate Life Cycle	TGAI	B	No		Reserved[3]	
72-5 - Fish Life Cycle	TGAI	B	No		Reserved[4]	
72-6 - Aquatic Organism Accumulation	TGAI	B	No		Yes	1 Year
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	B	No		Reserved[3]	

Table A
MCPA Acid Generic Data Requirements

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
§158.540 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	B	No		No	
NONTARGET AREA PHYTOTOXICITY						
TIER I						
121-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		No	
122-1 - Vegetative Vigor	TGAI	B	No			
122-2 - Aquatic Plant Growth	TGAI	B	No		No	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	B	No		Yes	1 Year
123-1 - Vegetative Vigor	TGAI	B	No		Yes	1 Year
123-2 - Aquatic Plant Growth	TGAI	B	No		Yes	1 Year
TIER III						
124-2 - Terrestrial Field Study	TEP	B	No		Reserved[5]	
124-2 - Aquatic Field Study	TEP	B	No		Reserved[5]	

Table A
MCPA Acid Generic Data Requirements

158.490 - 540 Footnotes

[1] Reserved pending receipt and evaluation of environmental fate studies.
[2] Formulated product testing is not required because this pesticide has no aquatic uses and the maximum estimated environmental concentration is not greater than the lowest LC_{50}.
[3] Reserved pending receipt and evaluation of acute toxicity and environmental fate studies.
[4] Reserved pending receipt and evaluation of fish early life stage or invertebrate life cycle studies, if required.
[5] Reserved pending receipt and evaluation of Tier II plant studies.
[6] Guidelines requirement for 48-hour LC_{50} for shrimp not fulfilled.

Table A

Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.490 - Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	A,B,C,G	No		Yes	1 Year
71-2 - Avian Dietary LC_{50}						
a. Upland Game Bird	TGAI	A,B,C,G	No		Yes	1 Year
b. Waterfowl	TGAI	A,B,C,G	No		Yes	1 Year
71-3 - Wild Mammal Toxicity	TGAI	A,B,C,G	No		No	
71-4 - Avian Reproduction	TGAI	A,B,C,G	No		Reserved[1]	
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TGAI	A,B,C,G	No		Reserved[2]	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}						
a. Coldwater	TGAI TEP	A,B,C,G C	Partially Partially	40062005 00041298,00026928, 00041297,00041299	Yes[5] Yes[6]	1 Year 1 Year
b. Warmwater	TGAI TEP	A,B,C,G C	No Partially	 00041298,00026928, 00041297,00041299	Yes Yes[6]	1 Year 1 Year
72-2 - Freshwater Aquatic Invertebrate LC_{50}	TGAI TEP	A,B,C,G C	No No		Yes Yes	1 Year 1 Year

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.490 - Wildlife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING (cont'd)						
72-3 - Estuarine/Marine Organism LC_{50}	TGAI TEP	A,C,G C	No No		Yes Yes	1 Year 1 Year
72-4 - Fish Early Life Stage/ Aquatic Invertebrate Life Cycle	TGAI	A,C,G	No		Reserved[2]	
72-5 - Fish Life Cycle	TGAI	A,C,G	No		Reserved[3]	
72-6 - Aquatic Organism Accumulation	TGAI	A,C,G	No		Yes	1 Year
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,C,G	No		Reserved[2]	
§158.540 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	A,C,G	No		No	

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisty This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
NONTARGET AREA PHYTOTOXICITY						
TIER I						
121-1 - Seed Germination/ Seedling Emergence	TGAI	A,C,G	No		No	
122-1 - Vegetative Vigor	TGAI	A,C,G	No		No	
122-2 - Aquatic Plant Growth	TGAI	A,C,G	No		No	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,C,G	No		Yes	1 Year
123-1 - Vegetative Vigor	TGAI	A,C,G	No		Yes	1 Year
123-2 - Aquatic Plant Growth	TGAI	A,C,G	No		Yes	1 Year
TIER III						
124-1 - Terrestrial Field Study	TEP	A,C,G	No		Reserved[4]	
124-2 - Aquatic Field Study	TEP	A,C,G	No		Reserved[5]	

Table A
Generic Data Requirements for Organic Amines/Esters of MCPA

158.490 - 540 Footnotes

[1] Reserved pending receipt and evaluation of environmental fate studies.
[2] Reserved pending receipt and evaluation of acute toxicity and environmental fate studies.
[3] Reserved pending receipt and evaluation of fish early life-stage of invertebrate life-cycle studies, if required.
[4] Reserved pending receipt and evaluation of Tier II plant studies.
[5] A rainbow trout study using 56.4% technical dimethylamine salt was submitted and found acceptable.
[6] Data are available to support 52% dimethylamine salt formulation for coldwater and warmwater fish.

Table A
MCPA Sodium Salt Generic Data Requirements

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.490 - Wildlife and Aquatic Organisms						
AVIAN AND MAMMALIAN TESTING						
71-1 - Avian Oral LD_{50}	TGAI	A,B,C	Yes	40019201	No	
71-2 - Avian Dietary LC_{50}						
a. Upland Game Bird	TGAI	A,B,C	Yes	00163844	No	
b. Waterfowl	TGAI	A,B,C	Yes	00163844	No	
71-3 - Wild Mammal Toxicity	TGAI	A,B,C	No		No	
71-4 - Avian Reproduction	TGAI	A,B,C	No		Reserved[1]	
71-5 - Simulated and Actual Field Testing - Mammals and Birds	TEP	A,B,C	No		Reserved[2]	
AQUATIC ORGANISM TESTING						
72-1 - Freshwater Fish LC_{50}						
a. Coldwater	TGAI	A,B,C	Yes	00041294,00041295, 00029654	No	
	TEP	C	Yes	00004512,00026927 00041300,00029655	Yes[3]	1 Year
b. Warmwater	TGAI	A,B,C	Yes	00041294,00041295, 00029654	No	
	TEP	C	Yes	00004512,00026927	Yes[3]	1 Year

Table A
MCPA Sodium Salt Generic Requirements (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.490 - Wildlife and Aquatic Organisms (cont'd)						
AQUATIC ORGANISM TESTING (cont'd)						
72-2 - Freshwater Aquatic Invertebrate LC_{50}	TGAI	A,B,C	Yes	00041294,00041295, 00029654	No	
	TEP	C	No		Yes[3]	1 Year
72-3 - Estuarine/Marine Organism LC_{50}	TGAI	A,B,C	Partially	40062002,40062003	Yes[6]	1 Year
	TEP	C	No		Yes[3]	1 Year
72-4 - Fish Early Life Stage/ Aquatic Invertebrate Life Cycle	TGAI	A,B,C	No		Reserved[2]	
72-5 - Fish Life Cycle	TGAI	A,B,C	No		Reserved[4]	
72-6 - Aquatic Organism Accumulation	TGAI	A,B,C	No		Yes	1 Year
72-7 - Simulated or Actual Field Testing - Aquatic Organisms	TEP	A,B,C	No		Reserved[2]	
§158.540 Plant Protection						
121-1 - TARGET AREA PHYTOTOXICITY	TEP	A,B,C	No		No	

Table A
MCPA Sodium Salt Generic Data Requirements (cont'd)

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe For Data Submission
§158.540 Plant Protection						
NONTARGET AREA PHYTOTOXICITY						
TIER I						
121-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C	No		No	
122-1 - Vegetative Vigor	TGAI	A,B,C	No		No	
122-2 - Aquatic Plant Growth	TGAI	A,B,C	No		No	
TIER II						
123-1 - Seed Germination/ Seedling Emergence	TGAI	A,B,C	No		Yes	1 Year
123-1 - Vegetative Vigor	TGAI	A,B,C	No		Yes	1 Year
123-2 - Aquatic Plant Growth	TGAI	A,B,C	No		Yes	1 Year
TIER III						
124-1 - Terrestrial Field Study	TEP	A,B,C	No		Reserved[5]	
124-2 - Aquatic Field Study	TEP	A,B,C	No		Reserved[5]	

Table A
MCPA Sodium Salt Generic Data Requirements (cont'd)

158.490 - 540 Footnotes - (cont'd)

[1] This study is required for technical MCPA acid and that study will support this requirement.
[2] Reserved pending receipt and evaluation of acute toxicity and environmental fate studies.
[3] Formulated product testing is required because this pesticide has aquatic uses.
[4] Reserved pending receipt and evaluation of fish early life-stage or invertebrate life-cycle studies, if required.
[5] Reserved pending receipt and evaluation of Tier II plant studies.
[6] Guideline requirement for 48-hour LC_{50} for shrimp (using technical MCPA acid) is not fulfilled.

Table A

Generic Data Requirements for MCPA, Dimethylamine Salt

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.590 - Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute LD_{50}	TGAI	A,B,G	No		Yes	1 Year
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,G	No		No[1]	
141-5 - Field Testing For Pollinators	TEP	A,B,G	No		No[1]	

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[1] Requirement deferred pending evaluation of data from the acute contact test.

Table A
Generic Data Requirements for MCPA, Isooctyl Ester

Data Requirement	Test Substance	Use Pattern	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.590 - Nontarget Insects						
NONTARGET INSECT TESTING - POLLINATORS						
141-1 - Honey Bee Acute Toxicity	TGAI	A,B,G	No		Yes	1 Year
141-2 - Honey Bee - Toxicity of Residues on Foliage	TEP	A,B,G	No		No[1]	
141-5 - Field Testing for Pollinators	TEP	A,B,G	No		No[1]	

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[1] Requirement deferred pending evaluation of data from the acute contact test.

Table B
Product Specific Data Requirements for MCPA, Manufacturing-Use Products

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.190 Product Chemistry					
Product Identity and Composition					
61-1 - Product Identity and Disclosure of Ingredients	MP	No	00159470,00154076, 00155743,00126755, 00155233	Yes[1]	1 Year
61-2 - Description of Beginning Materials and Manufacturing Process	MP	No	N/A	Yes[2]	1 Year
61-3 - Discussion of Formation of Impurities	MP	No	N/A	Yes[3]	1 Year
Analysis and Certification of Product Ingredients					
62-1 - Preliminary Analysis of Product Samples	MP	No	N/A	Yes[4]	1 Year
62-2 - Certification of Ingredient Limits	MP	No	00126755,00155233, 00154076,00159470, 00155743	Yes[5]	1 Year
62-3 - Analytical Methods to Verify Certified Limits	MP	No	00158078,00159470, 00154076,40212901, 00154064,40513001, 00126755,00155743, 00155234,40314402, 00105215,00079473, 00094623,	Yes[6]	1 Year

Table B

Product Specific Data Requirements for MCPA, Manufacturing-Use Products

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.190 - Product Chemistry (cont'd)					
Physical and Chemical Characteristics					
63-2 - Color	MP	No		Yes[7]	1 Year
63-3 - Physical State	MP	No		Yes[7]	1 Year
63-4 - Odor	MP	No		Yes[7]	1 Year
63-7 - Density, Bulk Density or Specific Gravity	MP	No		Yes[7]	1 Year
63-12 - pH	MP	No		Yes[7,8]	1 Year
62-14 - Oxidizing or Reducing Action	MP	No	00155743,00152836	Yes[7]	1 Year
62-15 - Flammability	MP	No	00155743,00159470, 00152836	Yes[7,9]	1 Year
63-16 - Explodability	MP	No	00155743,00126755, 00152836	Yes[7,10]	1 Year
63-17 - Storage Stability	MP	No	00155743,00159470 00126755,00152836	Yes[7]	2 Years
63-18 - Viscosity	MP	No		Yes[7,11]	1 Year
63-19 - Miscibility	MP	No	00126755	Yes[7,12]	1 Year

Table B
Product Specific Data Requirements for MCPA, Manufacturing-Use Products

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
Part 158.190 - Product Chemistry - (cont'd)					
Physical and Chemical Characteristics (cont'd)					
63-20 - Corrosion Characteristics	MP	No	00155743,00159470 00152836	Yes[7]	2 Years
Other Requirements					
64-1 - Submittal of Samples	N/A	N/A	N/A	No	

158.190 Footnotes - All numbers in parentheses refer to EPA registration numbers.

[1] Data regarding this topic is required for all manufacturing-use products except the Riverdale 94 percent T acid(228-200) and the 91 percent T isooctyl ester (228-198), and the BASF 93.6 percent T acid alternate formulation (7969-34). The requirements may be satisfied by selected information for the following products: (i) Upper and lower certified limits must be provided for the active ingredient and upper limits for each impurity or group of impurities for which a certified limit is required for products with EPA Registration Numbers listed parenthetically: the Rhone-Poulenc 92 percent (359-728) and 98 percent (359-721) T acids, and the 97 percent T butoxyethyl ester (359-738); the Kemisk Vaerk Koge A/S 95 percent T acid (EPA Reg. No. 11636-2); the A.H. Marks 93 percent T acids (15440-7 and -18), the 94.3 percent butoxyethyl ester (15440-8), and the 94 percent T isooctyl ester (15440-9); the Gilmore 95 percent T acid (42545-19), the 94 percent T isooctylester (42545-24 - basic formulation); and the Dow 64 percent FI dimethylamine salt (464-582), the 93.3 percent T butoxyethyl ester (464-595), and the 93.3 percent T isooctyl ester (464-585). Certifications must be submitted on EPA form 8570-4 (Rev. 2-85) for these products and for the: Gilmore 94 percent T isooctyl ester-alternate formulation (42545-24) and the 95 percent T acid (42545-9); the Dow 94 percent T acid (464-580); and the Kemisk Vaerk Koge A/S 92 percent T isooctyl ester (11636-3). (ii) Nominal concentrations are required for: the Dow 94 percent T acid (464-580); the PBI/Gordon 45.5 percent FI; the BASF 93.6 percent TR acid basic formulation (7969-34); and the Kemisk Vaerk Koge A/S 92 percent T isooctyl ester (EPA Reg. No. 11636-3). (iii) An updated CSF must be submitted for: the Rhone-Poulenc 92 percent (359-728) and 98 percent (359-721) Ts acids; the Marks 93 percent T acid (15440-18); the Gilmore 95 percent T acid (42545-19) and 94 percent T isooctyl ester basic formulation (42545-24) by the current registrant; (iv) The purpose of ingredients is required of all of the A.H. Marks technical products (15440-7, -18, -8,

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158.190 Footnotes

-9). (vi) Compounds present as a consequence of reactions of the manufacturing process must be listed as impurities rather than inerts on the CSFs for the following products: Kemisk Vaerk Koge A/S 95 percent T acid (11636-2); Gilmore 95 percent T acids (42545-9 and 42545-19), and the 94 percent T isooctyl ester (42545-24); the Rhone-Poulenc 97 percent butoxyethyl ester (359-738); the Dow 93 percent T isooctyl ester (464-585); and the 93 percent T butoxethyl ester (464-595).

[2] Complete information must be provided for the Dow 64 percent FI (464-582), the PBI/Gordon 45.5 percent FI (2217-722), the Dow 64 percent FI (464-582), the Denbro 74.38 percent FI (51907-20), the Inter-Ag 97 percent FI (57539-43), and the Platte 95 percent (34704-232) regarding the nature of the process (batch or continuous), the relative amounts of beginning materials and the order in which they are added, the chemical equations for each intended reaction, equipment used to produce each intermediate and the final product, reaction conditions, duration of each step of the process, purification procedures and quality control measures. In addition, the name and address of the manufacturer, producer, or supplier of each beginning material used in the manufacture of each product must be provided, along with information regarding the properties of those materials.

[3] A detailed discussion must be submitted for PBI/Gordon 45.5 percent FI (2217-722), the Dow 64 percent FI (464-582), the Denbro 74.38 percent FI (51907-20), the Inter-Ag 97 percent (57539-43), and the Platte 95 percent FI (34704-232) regarding all impurities that are or may be present at ≥ 0.1 percent, based on knowledge of the beginning materials, intended and side chemical reactions in the manufacturing process, and any contamination during and after production. A decision regarding the possible presence of dibenzo-p-dioxins, and dibenzofurans from any source in the product is also required. In addition, a discussion of the possible formation of nitrosamines is required for the 64 percent and 74.38 percent FI dimethylamine salts (464-582 and 51907-20).

[4] Five or more representative samples of the PBI/Gordon 45.5 percent FI, the Dow 64 percent FI dimethylamine salt (464-582), the Denbro 74.38 percent FI dimethylamine salt (51907-20), the Inter-Ag 97 percent FI (57539-43), and the Platte 95 percent FI mixed ester (34704-232) must be analyzed for the amount of active ingredient and each impurity for which certified limits are required. Complete, detailed descriptions of the analytical methods used must be submitted along with statements of their precision and accuracy. Reports of preliminary analyses should include for each sample the identity of each ingredient for which analysis was conducted, the quantity that was found, and the mean relative standard deviation of reported analytical results. In addition, six samples of the Dow and Denbro FI dimethylamine salt products must be analyzed for presence of nitrosamines by methods capable of detecting 1 ppm: two samples must be analyzed shortly after production, two samples at 3 months after production, and two samples at 6 months after production.

[5] Upper and lower limits for the active ingredient and each intentionally added inert, and upper limits for each impurity present at ≥ 0.1 percent (w/w, and each additional "toxicologically significant" impurity present at < 0.1 percent (w/w) must be provided and certified. An explanation of how each certified limit was established must be provided (e.g., sample analysis using validated analytical procedures, quantitative estimate based on amount of ingredients used, etc.). Fully validated methods (precision and accuracy) must be used to generate the data to support these limits. Limits for impurities not associated with the active ingredient need to be provided only if they are

Table B
Product Specific Data Requirements for MCPA, Manufacturing-Use Products

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158.190 Footnotes (cont'd)

considered to be of toxicological significance, regardless of the concentration at which they occur. Certifications must be submitted on EPA Form 8570 (Rev. 2-85). These data are required for all manufacturing-use products except the Riverdale 94 percent T acid (228-200), and the 91 percent T isooctyl ester (200-198), and the BASF 93.6 percent T acid alternate formulation (7969-34). The requirements may be satisfied for the following products by submission of validation data for precision and accuracy for the analytical methods used to verify certified limits: the Dow 94 percent T acid (EPA Reg. No. 464-580), the Gilmore 95 percent T acid (EPA Reg. No. 42545-9), and the Kemisk Vaerk Koge A/S 92 percent T isooctyl ester (EPA Reg. No. 11636-3).

[6] Analytical methods to determine the active ingredient and each impurity (including dibenzo-p-dioxins and dibenzofurans) and intentionally added inerts for which a certified limit is required must be submitted for all manufacturing-use products except the Riverdale 94 percent T acid (228-200) and 91 percent T isooctyl ester (228-198), and the BASF 93.5 percent T alternate formulation (7969-34). This requirement may be satisfied for the following products by submission of validated methods for additional impurities and validation studies depicting precision and accuracy of the available methods for active ingredient and impurities: the Rhone-Poulenc unspecified T acid; the Dow T acid (464-580), FI dimethylamine salt (464-582), and T isooctyl ester (464-585); the BASF T acid (7969-34); the Kemisk T acid 911636-2); an unspecified Marks T acid and esters; and the Gilmore T acid basic formulation (42545-9). Methods for quantification of nitrosamines are also required for the 64 percent and 74.38 percent FI dimethylamine salts (EPA Reg. Nos. 464-582 and 51907-20). Each method must be accompanied by validation studies indicating its accuracy and precision. These methods must be suitable for enforcement of certified limits.

[7] As required in the 40 CFR 158.120 and more fully described in the Pesticide Assessment Guidelines, Subdivision D, quantitative data regarding color, physical state, odor, specific gravity, pH, oxidizing/reducing action, flammability, explodability, storage stability, viscosity, miscibility, and corrosion characteristics for each manufacturing-use product except the Riverdale 94 percent T acid (228-200) and 91 percent T isooctyl ester (228-189), the BASF 93.6 percent T acid alternate formulation (11636-34), and the technical products for which certain of these data were requested in footnote 4 in Table A - Product Chemistry.

[8] Data on pH are required if the test substance can be diluted or dispersed in water.

[9] Data are required on the flashpoint if the product is or contains a combustible liquid.

[10] Data are required if the product contains any potentially explosive ingredients.

[11] Data on viscosity are required if the product is a liquid.

[12] Data on miscibility are required if the product is an emulsifiable liquid and is to be diluted with petroleum solvents.

Table B
Product-Specific Data Requirements for MCPA, Manufacturing-Use Products

Data Requirement	Test Substance	Does EPA Have Data to Satisfy This Requirement?	Bibliographic Citation	Must Additional Data Be Submitted Under FIFRA Section 3(c)(2)(B)?	Timeframe For Data Submission
158.340 - Toxicology					
ACUTE TESTING					
81-1 - Acute Oral - Rat	MP	No		Yes	2 Years
81-2 - Acute Dermal	MP	No		Yes	2 Years
81-3 - Acute Inhalation - Rat	MP	No		Yes	2 Years
81-4 - Primary Eye Irritation - Rabbit	MP	No		Yes	1 Year
81-5 - Primary Dermal Irritation	MP	No		Yes	1 Year
81-6 - Dermal Sensitization	MP	No		Yes	1 Year

Table C
Product Specific Data Requirements for MCPA - End-Use Products

Data Requirement	Test Substance	Use Patterns	Does EPA[1] Have Data?	Bibliographic Citation	Must Additional Data Be[2] Submitted?	Timeframe for Submission
40 CFR §158.155-190 Product Chemistry						
Product Composition						
61-1. Product Composition	EP		TBD[3]		Yes	1 Year
61-2. Beginning Materials Production or Formulation Process	EP		TBD		Yes	1 Year
61-3. Formation of Impurities	EP		TBD		Yes	1 Year
Analysis and Certification of Product Ingredients						
62-1. Preliminary Analysis	EP		TBD		Yes	1 Year
62-2. Certified Limits	EP		TBD		Yes	1 Year
62-3. Enforcement Analytical Methods	EP		TBD		Yes	1 Year

Table C
Product Specific Data Requirements for MCPA - End-Use Products

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
Physical and Chemical Characteristics						
63-2. Color	EP		TBD		Yes	1 Year
63-3. Physical State	EP		TBD		Yes	1 Year
63-4. Odor	EP		TBD		Yes	1 Year
63-7. Density, Bulk Density, or Specific Gravity	EP		TBD		Yes	1 Year
63-12. pH	EP		TBD		Yes	1 Year
62-14. Oxidizing or Reducing Action	EP		TBD		Yes	1 Year
62-15. Flammability	EP		TBD		Yes	1 Year
63-16. Explodability	EP		TBD		Yes	1 Year
63-17 Storage Stability	EP		TBD		Yes	2 Years

Table C
Product Specific Data Requirements for MCPA - End-Use Products

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
Physical and Chemical Characteristics (Continued)						
63-18. Viscosity	EP		TBD		Yes	1 Year
63-19. Miscibility	EP		TBD		Yes	1 Year
63-20. Corrosion Characteristics	EP		TBD		Yes	2 Years
Other Requirements:						
64-1. Submittal of Samples	N/A		N/A	N/A	No	

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[1] Registrants must inform the Agency whether acceptable data are available on each of their end-use products. Registrants may cite data which the Agency has previously informed them are acceptable or data which they believe to be acceptable. While the Agency makes the final determination of what constitutes "acceptable" data, guidance is offered in 40 CFR 158.80. In addition, 40 CFR 158.108 announces the avialability of guidelines for conducting acceptable tests. If acceptable data are available, registrants must cite the MRID or accession numbers; if acceptable data are not available, registrants must submit data within the time frames listed on this table.

[2] See above footnote.

[3] TBD=To be determined.

Table C
Product Specific Data Requirements for MCPA - End-Use Products

Data Requirement	Test Substance	Use Patterns	Does EPA Have Data?	Bibliographic Citation	Must Additional Data Be Submitted?	Timeframe for Submission
158.340 Toxicology - Acute Testing:						
81-1 - Acute Oral-Rat	EP	A,B	TBD[3]		Yes	2 Years
81-2 - Acute Dermal	EP	A,B	TBD		Yes	2 Years
81-3 - Acute Inhalation-Rat	EP	A,B	TBD		Yes	2 Years
81-4 - Eye Irritation-Rabbit	EP	A,B	TBD		Yes	1 Year
81-5 - Dermal Irritation-Rabbit	EP	A,B	TBD		Yes	1 Year
81-6 - Dermal Sensitization - Guinea Pig	EP	A,B	TBD		Yes	1 Year
81-7 - Acute Delayed Neurotoxicity-Hen	EP	A,B	No		No[4]	

[1] Registrants must inform the Agency whether acceptable data are available on each of their end-use products. Registrants may cite data which the Agency has previously informed them are acceptable or data which they believe to be acceptable. While the Agency makes the final determination of what constitutes "acceptable" data, guidance is offered in 40 CFR 158.108. In addition, 40 CFR 158.108 announces the avialability of guidelines for conducting acceptable tests. If acceptable data are available, registrants must cite the MRID or accession numbers; if acceptable data are not avialable, registrants must submit data within the time frames listed above.

[2] See above footnote.

[3] TBD = To be determined.

[4] An acute neurotoxicity study is not required since MCPA is not an organophosphate.

II. LABELING APPENDICES

SUMMARY-1

LABEL CONTENTS

40 CFR 156.10 requires that certain specific labeling statements appear at certain locations on the label. This is referred to as format labeling. Specific label items listed below are keyed to the table at the end of this Appendix.

Item 1. PRODUCT NAME - The name, brand or trademark is required to be located on the front panel, preferably centered in the upper part of the panel. The name of a product will not be accepted if it is false or misleading.

Item 2. COMPANY NAME AND ADDRESS - The name and address of the registrant or distributor is required on the label. The name and address should preferably be located at the bottom of the front panel or at the end of the label text.

Item 3. NET CONTENTS - A net contents statement is required on all labels or on the container of the pesticide. The preferred location is the bottom of the front panel immediately above the company name and address, or at the end of the label test. The net contents must be expressed in the largest suitable unit, e.g., "1 pound 10 ounces" rather than "26 ounces." In addition to English units, net contents may be expressed in metric units. [40 CFR 156.10(d)]

Item 4. EPA REGISTRATION NUMBER - The registration number assigned to the pesticide product must appear on the label, preceded by the phrase "EPA Registration No.," or "EPA Reg. No." The registration number must be set in type of a size and style similar to other print on that part of the label on which it appears and must run parallel to it. The registration number and the required identifying phrase must not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency. [40 CFR 156.10(e)]

Item 5. EPA ESTABLISHMENT NUMBER - The EPA establishment number, preceded by the phrase "EPA Est." is the final establishment at which the product was produced, and may appear in any suitable location on the label or immediate container. It must also appear on the wrapper or outside container of the package if the EPA establishment number on the immediate container cannot be clearly read through such wrapper or container. [40 CFR 156.10(f)]

SUMMARY-2

Item 6A. INGREDIENTS STATEMENT - An ingredients statement is required on the front panel. The ingredients statement must contain the name and percentage by weight of each active ingredient and the total percentage by weight of all inert ingredients. The preferred location is immediately below the product name. The ingredients statement must run parallel with, and be clearly distinguished from, other text on the panel. It must not be placed in the body of other text. [40 CFR 156.10(g)]

Item 6B. POUNDS PER GALLON STATEMENT - For liquid agricultural formulations, the pounds per gallon of active ingredient must be indicated on the label.

Item 7. FRONT LABEL PRECAUTIONARY STATEMENTS - Front panel precautionary statements must be grouped together, preferably within a block outline. The table below shows the minimum type size requirements for various size labels.

Size of Label on Front Panel in Square Inches	Signal Word Minimum Type Size All Capitals	"Keep Out of Reach of Children" Minimum Type Size
5 and under	6 point	6 point
above 5 to 10	10 point	6 point
above 10 to 15	12 point	8 point
above 15 to 30	14 point	10 point
over 30	18 point	12 point

Item 7A. CHILD HAZARD WARNING STATEMENT - The statement "Keep Out of Reach of Children" must be located on the front panel above the signal word except where contact with children during distribution or use is unlikely.
[40 CFR 156.10(h)(1)(ii)]

Item 7B. SIGNAL WORD - The signal word (DANGER, WARNING, or CAUTION) is required on the front panel immediately below the child hazard warning statement.
[40CFR 156.10(h)(1)(i)].

Item 7C. SKULL & CROSSBONES AND WORD "POISON" - On products assigned a toxicity Category I on the basis of oral, dermal, or inhalation toxicity, the word "Poison" shall appear on the label in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word POISON.
[40 CFR 156.10(h)(1)(i)].

Item 7D. STATEMENT OF PRACTICAL TREATMENT - A statement of practical treatment (first aid or other) shall appear on the label of pesticide products in toxicity Categories I, II, and III. [40 CFR 156.10(h)(1)(iii)]

Item 7E. REFERRAL STATEMENT - The statement "see Side (or Back) Panel for Additional Precautionary Statements" is required on the front panel for all products, unless all required precautionary statements appear on the front panel. [40 CFR 156.10(h)(1)(iii)].

Item 8. SIDE/BACK PANEL PRECAUTIONARY LABELING - The precautionary statements listed below must appear together on the label under the heading "PRECAUTIONARY STATEMENTS." The preferred location is at the top of the side or back panel preceding the directions for use, and it is preferred that these statements be surrounded by a block outline. Each of the three hazard warning statements must be headed by the appropriate hazard title. [40 CFR 156.10(h)(2)]

Item 8A. HAZARD TO HUMANS AND DOMESTIC ANIMALS - Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. [40 CFR 156.10(h)(2)(i)]

Item 8B. ENVIRONMENTAL HAZARD - Where a hazard exists to non-target organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury, or damage. [40 CFR 156.10(h)(2)(ii)]

Item 8C. PHYSICAL OR CHEMICAL HAZARD - FLAMMABILITY Precautionary statements relating to flammability of a product are required to appear on the label if it meets the criteria in the PHYS/CHEM Labeling Appendix. The requirement is based on the results of the flashpoint determinations and flame extension tests required to be submitted for all products. These statements are to be located in the side/back panel precautionary statements section, preceded by the heading "Physical/Chemical Hazards." Note that no signal word is used in conjunction with the flammability statements.

Item 9A. RESTRICTED USE CLASSIFICATION - FIFRA sec. 3(d) requires that all pesticide formulations/uses be classified for either general or restricted use. Products classified for restricted use may be limited to use by certified applicators or persons under their direct supervision (or may be subject to other restrictions that may be imposed by regulation).

In the Registration Standard, the Agency has (1) indicated certain formulations/uses are to be restricted (Section IV indicates why the product has been classified for restricted use); or (2) reserved any classification decision until appropriate data are submitted.

The Regulatory Position and Rationale states whether products containing this active ingredient are classified for restricted use. If they are restricted the draft label(s) submitted to the Agency as part of your application must reflect this determination (see below).

If you do not believe that your product should be classified for restricted use, you must submit any information and rationale with your application for reregistration. During the Agency's review of your application, your proposed classification determination will be evaluated in accordance with the provisions of 40 CFR 162.11(c). You will be notified of the Agency's classification decision.

Classification Labeling Requirements

If your product has been classified for restricted use, the following label requirements apply:

1. All uses restricted.

   a. The statement "Restricted Use Pesticide" must appear at the top of the front panel of the label. The statement must be set in type of the same minimum size as required for human hazard signal word (see table in 40 CFR 156.10(h)(1)(iv).

   b. Directly below this statement on the front panel, a summary statement of the terms of restriction must appear (including the reasons for restriction if specified in Section I). If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's Certification."

2. Some but not all uses restricted. If the Regulatory Position and Rationale states that some uses are classified for restricted use, and some are unclassified, several courses of action are available:

   a. You may label the product for Restricted use. If you do so, you may include on the label uses that are unrestricted, but you may not distinguish them on the label as being unrestricted.

b. You may delete all restricted uses from your label and submit draft labeling bearing only unrestricted uses.

c. You may "split" your registration, i.e., register two separate products with identical formulations, one bearing only unrestricted uses, and the other bearing restricted uses. To do so, submit two applications for reregistration, each containing all forms and necessary labels. Both applications should be submitted simultaneously. Note that the products will be assigned separate registration numbers.

Item 9B. MISUSE STATEMENT - All products must bear the misuse statement, "It is a violation of Federal law to use this product in a manner inconsistent with its labeling." This statement appears at the beginning of the directions for use, directly beneath the heading of that section.

Item 10A. REENTRY STATEMENT - If a reentry interval has been established by the Agency, it must be included on the label. Additional worker protection statements may be required in accordance with PR Notice 83-2, March 29, 1983.

Item 10B. STORAGE AND DISPOSAL BLOCK - All labels are required to bear storage and disposal statements. These statements are developed for specific containers, sizes, and chemical content. These instructions must be grouped and appear under the heading "Storage and Disposal" in the directions for use. This heading must be set in the same type sizes as required for the child hazard warning. Refer to Appendix II, STOR, PEST/DIS, and CONT/DIS to determine the storage and disposal instructions appropriate for your products.

Item 10C. DIRECTIONS FOR USE - Directions for use must be stated in terms which can be easily read and understood by the average person likely to sue or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment. [40 CFR 156.10]

COLLATERAL LABELING

Bulletins, leaflets, circulars, brochures, data sheets, flyers, or other written or graphic printed matter which is referred to on the label or which is to accompany the product are termed collateral labeling. Such labeling may not bear claims or representations that differ in substance from those accepted in connection with registration of the product. It should be made part of the response to this notice and submitted for review.

SUMMARY-7

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL REQUIRED	PLACEMENT ON LABEL PREFERRED	COMMENTS
1	Product name	All products	Front panel	Center front panel	
2	Company name and address	All products	None	Bottom front panel or end of label text	If registrant is not the producer, must be qualified by "Packed for . . .," "Distributed by . . . ." etc.
3	Net contents	All products	None	Bottom front panel or end of label text	May be in metric units in addition to U.S. units.
4	EPA Reg. No.	All products	None	Front panel	Must be in similar type size and run parallel to other type.
5	EPA Est. No.	All products	None	Front panel immediately before or following Reg. No.	May appear on the container instead of the label.
6A	Ingredients statement	All products	Front panel	Immediately following product name	Text must run parallel with other text on the panel.
6B	Pounds/gallon statement	Liquid products where dosage is given as lbs. ai/unit area	Front panel	Directly below the main ingredients statement	
7	Front panel precautionary statements	All products	Front panel		All front panel precautionary statements must be grouped together, preferably blocked.
7A	Keep Out of Reach of Children (Child hazard warning)	All products	Front panel	Above signal word	Note type size requirements.
7B	Signal word	All products	Front panel	Immediately below child hazard warning	Note type size requirements.

SUMMARY-8

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
7C	Skull & crossbones and word POISON (in red)	All products which are Category I based on oral, dermal, or inhalation toxicity	Front panel	Both in close proximity to signal word	
7D	Statement of Practical Treatment or First Aid	All products in Categories I, II, and III	Category I: Front panel unless referral statement is used. Others: Grouped with side panel precautionary statements.	Front panel for all	
7E	Referral statement	All products where precautionary labeling appears on other than front panel	Front panel		
8	Side/back panel precautionary statements	All products	None	Top or side of back panel preceding directions for use	Must be grouped under headings in 8A, 8B, and 8C; preferably blocked.
8A	Hazards to humans and domestic animals	All products in Categories I, II, and III	None	Same as above	Must be preceded by appropriate signal word.
8B	Environmental hazards	All products	None	Same as above	Environmental hazards include bee caution where applicable.

SUMMARY-9

LABELING REQUIREMENTS OF THE FIFRA, AS AMENDED (cont'd)

ITEM	LABEL ELEMENT	APPLICABILITY OF REQUIREMENT	PLACEMENT ON LABEL		COMMENTS
			REQUIRED	PREFERRED	
8C	Physical or chemical hazards	All pressurized products, others with flash points under 150°F	None	Same as above	Refer to Appendix II guide PHYS/CHEM
9A	Restricted block	All restricted products	Top center of front panel	Preferably blocked	Includes a statement of the terms of restriction. The words "RESTRICTED USE PESTICIDE" must be same type size as signal word.
9B	Misuse statement	All products	Immediately following heading of directions for use		Required statement is: "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."
10A	Reentry statement	PR Notice 83-2 or as determined by the Agency	In the directions for use	Immediately after misuse statement	
10B	Storage and disposal block	All products	In the directions for use	Immediately before specific directions for use or at the end of directions for use	Must be set apart and clearly distinguishable from other directions for use. Refer to Appendix II guides STOR, CONT/DIS, and PEST/DIS for further information and required statements.
10C	Directions for use	All products	None	None	May be in metric as well as U.S. units

§156.10 Labeling Requirements for Pesticides and Devices.

(a) General--(1) Contents of the label. Every pesticide product shall bear a label containing the information specified by the Act and the regulations in this Part. The contents of a label must show clearly and prominently the following:

(i) The name, brand, or trademark under which the product is sold as prescribed in paragraph (b) of this section;

(ii) The name and address of the producer, registrant, or person for whom produced as prescribed in paragraph (c) of this section;

(iii) The net contents as prescribed in paragraph (d) of this section;

(iv) The product registration number as prescribed in paragraph (e) of this section;

(v) The producing establishment number as prescribed in paragraph (f) of this section;

(vi) An ingredient statement as prescribed in paragraph (g) of this section;

(vii) Warning or precautionary statements as prescribed in paragraph (h) of this section;

(viii) The directions for use as prescribed in paragraph (i) of this section; and

(ix) The use classification(s) as prescribed in paragraph (j) of this section.

(2) Prominence and legibility. (i) All words, statements, graphic representations, designs or other information required on the labeling by the Act or the regulations in this part must be clearly legible to a person with normal vision, and must be placed with such conspicuousness (as compared with other words, statements, designs, or graphic matter on the labeling) and expressed in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(ii) All required label text must:

(A) Be set in 6-point or larger type;

(B) Appear on a clear contrasting background; and

(C) Not be obscured or crowded.

(3) Language to be used. All required label or labeling text shall appear in the English language. However, the Agency may require or the applicant may propose additional text in other languages as is considered necessary to protect the public. When additional text in another language is necessary, all labeling requirements will be applied equally to both the English and other-language versions of the labeling.

(4) Placement of Label--(i) General. The label shall appear on or be securely attached to the immediate container of the

pesticide product. For purposes of this Section, and the misbranding provisions of the Act, "securely attached" shall mean that a label can reasonably be expected to remain affixed during the foreseeable conditions and period of use. If the immediate container is enclosed within a wrapper or outside container through which the label cannot be clearly read, the label must also be securely attached to such outside wrapper or container, if it is a part of the package as customarily distributed or sold.

(ii) Tank cars and other bulk containers--(A) Transportation. While a pesticide product is in transit, the appropriate provisions of 49 CFR Parts 170-189, concerning the transportation of hazardous materials, and specifically those provisions concerning the labeling, marking and placarding of hazardous materials and the vehicles carrying them, define the basic Federal requirements. In addition, when any registered pesticide product is transported in a tank car, tank truck or other mobile or portable bulk container, a copy of the accepted label must be attached to the shipping papers, and left with the consignee at the time of delivery.

(B) Storage. When pesticide products are stored in bulk containers, whether mobile or stationary, which remain in the custody of the user, a copy of the label or labeling, including all appropriate directions for use, shall be securely attached to the container in the immediate vicinity of the discharge control valve.

(5) False or misleading statements. Pursuant to section 2(q)(1)(A) of the Act, a pesticide or a device declared subject to the Act pursuant to §162.15, is misbranded if its labeling is false or misleading in any particular including both pesticidal and non-pesticidal claims. Examples of statements or representations in the labeling which constitute misbranding include:

(i) A false or misleading statement concerning the composition of the product;

(ii) A false or misleading statement concerning the effectiveness of the product as a pesticide or device;

(iii) A false or misleading statement about the value of the product for purposes other than as a pesticide or device;

(iv) A false or misleading comparison with other pesticides or devices;

(v) Any statement directly or indirectly implying that the pesticide or device is recommended or endorsed by any Agency of the Federal Government;

(vi) The name of a pesticide which contains two or more principal active ingredients if the name suggests one or more but not all such principal active ingredients even though the names of the other ingredients are stated elsewhere in the labeling;

(vii) A true statement used in such a way as to give a false or misleading impression to the purchaser;

(viii) Label disclaimers which negate or detract from labeling statements required under the Act and these regulations;

(ix) Claims as to the safety of the pesticide or its ingredients, including statements such as "safe," "nonpoisonous," "noninjurious," "harmless" or "nontoxic to humans and pets" with or without such a qualifying phrase as "when used as directed;" and

(x) Non-numerical and/or comparative statements on the safety of the product, including but not limited to:

(A) "Contains all natural ingredients";
(B) "Among the least toxic chemicals known"; and
(C) "Pollution approved."

(6) Final printed labeling. (i) Except as provided in paragraph (a)(6)(ii) of this section, final printed labeling must be submitted and accepted prior to registration. However, final printed labeling need not be submitted until draft label texts have been provisionally accepted by the Agency.

(ii) Clearly legible reproductions or photo reductions will be accepted for unusual labels such as those silk-screened directly onto glass or metal containers or large bag or drum labels. Such reproductions must be of microfilm reproduction quality.

(b) Name, brand, or trademark. (1) The name, brand, or trademark under which the pesticide product is sold shall appear on the front panel of the label.

(2) No name, brand, or trademark may appear on the label which:

(i) Is false or misleading, or

(ii) Has not been approved by the Administrator through registration or supplemental registration as an additional name pursuant to §162.6(b)(4).

(c) Name and address of producer, registrant, or person for whom produced. An unqualified name and address given on the label shall be considered as the name and address of the producer. If the registrant's name appears on the label and the registrant is not the producer, or if the name of the person for whom the pesticide was produced appears on the label, it must be qualified by appropriate wording such as "Packed for ***," "Distributed by ***," or "Sold by ***" to show that the name is not that of the producer.

(d) Net weight or measure of contents. (1) The net weight or measure of content shall be exclusive of wrappers or other materials and shall be the average content unless explicitly stated as a minimum quantity.

(2) If the pesticide is a liquid, the net content statement shall be in terms of liquid measure at 68 degrees F (20 degrees C) and shall be expressed in conventional American units of fluid ounces, pints, quarts, and gallons.

(3) If the pesticide is solid or semisolid, viscous or pressurized, or is a mixture of liquid and solid, the net content statement shall be in terms of weight expressed as avoirdupois pounds and ounces.

(4) In all cases, net content shall be stated in terms of the largest suitable unit, i.e., "1 pound 10 ounces" rather than "26 ounces."

(5) In addition to the required units specified, net content may be expressed in metric units.

(6) Variation above minimum content or around an average is permissible only to the extent that it represents deviation unavoidable in good manufacturing practice. Variation below a stated minimum is not permitted. In no case shall the average content of the packages in a shipment fall below the stated average content.

(e) Product registration number. The registration number assigned to the pesticide product at the time of registration shall appear on the label, preceded by the phrase "EPA Registration No.," or the phrase "EPA Reg. No." The registration number shall be set in type of a size and style similar to other print on that part of the label on which it appears and shall run parallel to it. The registration number and the required identifying phrase shall not appear in such a manner as to suggest or imply recommendation or endorsement of the product by the Agency.

(f) Producing establishment registration number. The producing establishment registration number preceded by the phrase "EPA Est.," of the final establishment at which the product was produced may appear in any suitable location on the label or immediate container. It must appear on the wrapper or outside container of the package if the EPA establishment registration number on the immediate container cannot be clearly read through such wrapper or container.

(g) Ingredient statement--(1) General. The label of each pesticide product must bear a statement which contains the name and percentage by weight of each active ingredient, the total percentage by weight of all inert ingredients; and if the pesticide contains arsenic in any form, a statement of the percentages of total and water-soluble arsenic calculated as elemental arsenic. The active ingredients must be designated by the term "active ingredients" and the inert ingredients by the term "inert ingredients," or the singular forms of these terms when appropriate. Both terms shall be in the same type size, be aligned to the same margin and be equally prominent. The statement "Inert Ingredients, none" is not required for pesticides which contain 100 percent active ingredients. Unless the ingredient statement is a complete analysis of the pesticide, the term "analysis" shall not be used as a heading for the ingredient statement.

(2) Position of ingredient statement. (i) The ingredient statement is normally required on the front panel of the label. If there is an outside container or wrapper through which the ingredient statement cannot be clearly read, the ingredient statement must also appear on such outside container or wrapper. If the size or form of the package makes it impracticable to place the ingredient statement on the front panel of the label, permission may be granted for the ingredient statement to appear elsewhere.

(ii) The text of the ingredient statement must run parallel with other text on the panel on which it appears, and must be clearly distinguishable from and must not be placed in the body of other text.

(3) Names to be used in ingredient statement. The name used for each ingredient shall be the accepted common name, if there is one, followed by the chemical name. The common name may be used alone only if it is well known. If no common name has been established, the chemical name alone shall be used. In no case will the use of a trademark or proprietary name be permitted unless such name has been accepted as a common name by the Administrator under the authority of Section 25(c)(6).

(4) Statements of percentages. The percentages of ingredients shall be stated in terms of weight-to-weight. The sum of percentages of the active and the inert ingredients shall be 100. Percentages shall not be expressed by a range of values such as "22-25%." If the uses of the pesticide product are expressed as weight of active ingredient per unit area, a statement of the weight of active ingredient per unit volume of the pesticide formulation shall also appear in the ingredient statement.

(5) Accuracy of stated percentages. The percentages given shall be as precise as possible reflecting good manufacturing practice. If there may be unavoidable variation between manufacturing batches, the value stated for each active ingredient shall be the lowest percentage which may be present.

(6) Deterioration. Pesticides which change in chemical composition significantly must meet the following labeling requirements:

(i) In cases where it is determined that a pesticide formulation changes chemical composition significantly, the product must bear the following statement in a prominent position on the label: "Not for sale or use after [date]."

(ii) The product must meet all label claims up to the expiration time indicated on the label.

(7) Inert ingredients. The Administrator may require the name of any inert ingredient(s) to be listed in the ingredient statement if he determines that such ingredient(s) may pose a hazard to man or the environment.

(h) Warnings and precautionary statements. Required warnings and precautionary statements concerning the general areas of toxicological hazard including hazard to children, environmental hazard, and physical or chemical hazard fall into two groups: those required on the front panel of the labeling and those which may appear elsewhere. Specific requirements concerning content, placement, type size, and prominence are given below.

(1) Required front panel statements. With the exception of the child hazard warning statement, the text required on the front panel of the label is determined by the Toxicity Category of the pesticide. The category is assigned on the basis of the highest hazard shown by any of the indicators in the table below:

Hazard Indicators	Toxicity Categories			
	I	II	III	IV
Oral LD_{50}	Up to and including 50 mg/kg	From 50 thru 500 mg/kg	From 500 thru 5000 mg/kg	Greater than 5000 mg/kg
Inhalation LC_{50}	Up to and including .2 mg/liter	From .2 thru 2 mg/liter	From 2 thru 20 mg/liter	Greater than 20 mg/liter
Dermal LD_{50}	Up to and including 200 mg/kg	From 200 thru 2000	From 2000 thru 20,000	Greater than 20,000
Eye effects	Corrosive; corneal opacity not reversible within 7 days	Corneal opacity reversible within 7 days; irritation persisting for 7 days	No corneal opacity; irritation reversible within 7 days	No irritation
Skin effects	Corrosive	Severe irritation at 72 hours	Moderate irritation at 72 hours	Mild or slight irritation at 72 hours

(i) Human hazard signal word--(A) Toxicity Category I. All pesticide products meeting the criteria of Toxicity Category I shall bear on the front panel the signal word "Danger." In addition if the product was assigned to Toxicity Category I on the basis of its oral, inhalation or dermal toxicity (as distinct from skin and eye local effects) the word "Poison" shall appear in red on a background of distinctly contrasting color and the skull and crossbones shall appear in immediate proximity to the word "Poison."

(B) Toxicity Category II. All pesticide products meeting the criteria of Toxicity Category II shall bear on the front panel the signal word "Warning."

(C) Toxicity Category III. All pesticide products meeting the criteria of Toxicity Category III shall bear on the front panel the signal word "Caution."

(D) Toxicity Category IV. All pesticide products meeting the criteria of Toxicity Category IV shall bear on the front panel the signal word "Caution."

(E) Use of signal words. Use of any signal word(s) associated with a higher Toxicity Category is not permitted except when the Agency determines that such labeling is necessary to prevent unreasonable adverse effects on man or the environment. In no case shall more than one human hazard signal word appear on the front panel of a label.

(ii) Child hazard warning. Every pesticide product label shall bear on the front panel the statement "Keep out of reach of children." Only in cases where the likelihood of contact with children during distribution, marketing, storage or use is demonstrated by the applicant to be extremely remote, or if the nature of the pesticide is such that it is approved for use on infants or small children, may the Administrator waive this requirement.

(iii) Statement of practical treatment--(A) Toxicity Category I. A statement of practical treatment (first aid or other) shall appear on the front panel of the label of all pesticides falling into Toxicity Category I on the basis of oral, inhalation or dermal toxicity. The Agency may, however, permit reasonable variations in the placement of the statement of practical treatment is some reference such as "See statement of practical treatment on back panel" appears on the front panel near the word "Poison" and the skull and crossbones.

(B) Other toxicity categories. The statement of practical treatment is not required on the front panel except as described in paragraph (h)(1)(iii)(A) of this section. The applicant may, however, include such a front panel statement at his option. Statements of practical treatment are, however, required elsewhere on the label in accord with paragraph (h)(2) of this section if they do not appear on the front panel.

(iv) Placement and prominence. All the required front panel warning statements shall be grouped together on the label, and shall appear with sufficient prominence relative to other front panel text and graphic material to make them unlikely to be overlooked under customary conditions of purchase and use. The following table shows the minimum type size requirements for the front panel warning statements on various sizes of labels:

Size of Label Front Panel in Square Inches	Points	
	Required signal word, all capitals	"Keep out of reach of Children"
5 and under	6	6
Above 5 to 10	10	6
Above 10 to 15	12	8
Above 15 to 30	14	10
Over 30	18	12

(2) Other required warnings and precautionary statements. The warnings and precautionary statements as required below shall appear together on the label under the general heading "Precautionary Statements" and under appropriate subheadings of "Hazard to Humans and Domestic Animals," "Environmental Hazard" and "Physical or Chemical Hazard."

(i) Hazard to humans and domestic animals. (A) Where a hazard exists to humans or domestic animals, precautionary statements are required indicating the particular hazard, the route(s) of exposure and the precautions to be taken to avoid accident, injury or damage. The precautionary paragraph shall be immediately preceded by the appropriate hazard signal word.

(B) The following table depicts typical precautionary statements. These statements must be modified or expanded to reflect specific hazards.

Toxicity Category	Precautionary Statements by Toxicity Category	
	Oral, Inhalation, or Dermal Toxicity	Skin and Eye Local Effects
I . . .	Fatal (poisonous) if swallowed [inhaled or absorbed through skin]. Do not breathe vapor [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Front panel statement of practical treatment required.]	Corrosive, causes eye and skin damage [or skin irritation]. Do not get in eyes, on skin, or on clothing. Wear goggles or face shield and rubber gloves when handling. Harmful or fatal if swallowed. [Appropriate first aid statement required.]
II . . .	May be fatal if swallowed [inhaled or absorbed through the skin]. Do not breathe vapors [dust or spray mist]. Do not get in eyes, on skin, or on clothing. [Appropriate first aid statements required.]	Causes eye [and skin] irritation. Do not get in eyes, on skin, or on clothing. Harmful if swallowed. [Appropriate first aid statement required.]
III . . .	Harmful if swallowed [inhaled or absorbed through the skin]. Avoid breathing vapors [dust or spray mist]. Avoid contact with skin [eyes or clothing]. [Appropriate first aid statement required.]	Avoid contact with skin, eyes, or clothing. In case of contact immediately flush eyes or skin with plenty of water. Get medical attention if irritation persists.
IV . . .	[No precautionary statements required.]	[No precautionary statements required.]

(ii) Environmental hazards. Where a hazard exists to nontarget organisms excluding humans and domestic animals, precautionary statements are required stating the nature of the hazard and the appropriate precautions to avoid potential accident, injury or damage. Examples of the hazard statements and the circumstances under which they are required follow:

(A) If a pesticide intended for outdoor use contains an active ingredient with a mammalian acute oral LD_{50} of 100 or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(B) If a pesticide intended for outdoor use contains an active ingredient with a fish acute LC_{50} of 1 ppm or less, the statement "This Pesticide is Toxic to Fish" is required.

(C) If a pesticide intended for outdoor use contains an active ingredient with an avian acute oral LD_{50} of 100 mg/kg or less, or a subacute dietary LC_{50} of 500 ppm or less, the statement "This Pesticide is Toxic to Wildlife" is required.

(D) If either accident history or field studies demonstrate that use of the pesticide may result in fatality to birds, fish or mammals, the statement "This pesticide is extremely toxic to wildlife (fish)" is required.

(E) For uses involving foliar application to agricultural crops, forests, or shade trees, or for mosquito abatement treatments, pesticides toxic to pollinating insects must bear appropriate label cautions.

(F) For all outdoor uses other than aquatic applications the label must bear the caution "Keep out of lakes, ponds or streams. Do not contaminate water by cleaning of equipment or disposal of wastes."

(iii) Physical or chemical hazards. Warning statements on the flammability or explosive characteristics of the pesticide are required as follows:

Flashpoint	Required Text
(A) PRESSURIZED CONTAINERS	
Flashpoint at or below 20 degrees F; if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
Flashpoint above 20 degrees F and not over 80 degrees F the flame extension is more than 18 inches long at a distance of 6 inches from the flame.	Flammable. Contents under pressure. Keep away from heat, sparks, and open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
All other pressurized containers	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130 degrees F may cause bursting.
(B) NONPRESSURIZED CONTAINERS	
At or below 20 degrees	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
Above 20 degrees F and not over 80 degrees F	Flammable. Keep away from heat and open flame.
Above 80 degrees F and not over 150 degrees F	Do not use or store near heat or open flame.

(i) Directions for Use--(1) General requirements--(i) Adequacy and clarity of directions. Directions for use must be stated in terms which can be easily read and understood by the average person likely to use or to supervise the use of the pesticide. When followed, directions must be adequate to protect the public from fraud and from personal injury and to prevent unreasonable adverse effects on the environment.

(ii) Placement of directions for use. Directions may appear on any portion of the label provided that they are conspicuous enough to be easily read by the user of the pesticide product. Directions for use may appear on printed or graphic matter which accompanies the pesticide provided that:

(A) If required by the Agency, such printed or graphic matter is securely attached to each package of the pesticide, or placed within the outside wrapper or bag;

(B) The label bears a reference to the directions for use in accompanying leaflets or circulars, such as "See directions in the enclosed circular"; and

(C) The Administrator determines that it is not necessary for such directions to appear on the label.

(iii) Exceptions to requirement for directions for use--(A) Detailed directions for use may be omitted from labeling of pesticides which are intended for use only by manufacturers of products other than pesticide products in their regular manufacturing processes, provided that:

(1) The label clearly shows that the product is intended for use only in manufacturing processes and specifies the type(s) of products involved.

(2) Adequate information, such as technical data sheets or bulletins, is available to the trade specifying the type of product involved and its proper use in manufacturing processes;

(3) The product will not come into the hands of the general public except after incorporation into finished products; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(B) Detailed directions for use may be omitted from the labeling of pesticide products for which sale is limited to physicians, veterinarians, or druggists, provided that:

(1) The label clearly states that the product is for use only by physicians or veterinarians;

(2) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment; and

(3) The product is also a drug and regulated under the provisions of the Federal Food, Drug, and Cosmetic Act.

(C) Detailed directions for use may be omitted from the labeling of pesticide products which are intended for use only by formulators in preparing pesticides for sale to the public, provided that:

(1) There is information readily available to the formulators on the composition, toxicity, methods of use, applicable

restrictions or limitations, and effectiveness of the product for pesticide purposes;

(2) The label clearly states that the product is intended for use only in manufacturing, formulating, mixing, or repacking for use as a pesticide and specifies the type(s) of pesticide products involved;

(3) The product as finally manufactured, formulated, mixed, or repackaged is registered; and

(4) The Administrator determines that such directions are not necessary to prevent unreasonable adverse effects on man or the environment.

(2) Contents of Directions for Use. The directions for use shall include the following, under the heading "Directions for Use""

(i) The statement of use classification as prescribed in 162.10(j) immediately under the heading "Directions for Use."

(ii) Immediately below the statement of use classification, the statement "It is a violation of Federal law to use this product in a manner inconsistent with its labeling."

(iii) The site(s) of application, as for example the crops, animals, areas, or objects to be treated.

(iv) The target pest(s) associated with each site.

(v) The dosage rate associated with each site and pest.

(vi) The method of application, including instructions for dilution, if required, and type(s) of application apparatus or equipment required.

(vii) The frequency and timing of applications necessary to obtain effective results without causing unreasonable adverse effects on the environment.

(viii) Specific limitations on reentry to areas where the pesticide has been applied, meeting the requirements concerning reentry provided by 40 CFR Part 170.

(ix) Specific directions concerning the storage and disposal of the pesticide and its container, meeting the requirements of 40 CFR Part 165. These instructions shall be grouped and appear under the heading "Storage and Disposal." This heading must be set in type of the same minimum sizes as required for the child hazard warning (See Table in §162.10(h)(1)(iv).)

(x) Any limitations or restrictions on use required to prevent unreasonable adverse effects, such as:

(A) Required intervals between application and harvest of food or feed crops.

(B) Rotational crop restrictions.

(C) Warnings as required against use on certain crops, animals, objects, or in or adjacent to certain areas.

(D) [Reserved]

(E) For restricted use pesticides, a statement that the pesticide may be applied under the direct supervision of a certified applicator who is not physically present at the site of application but nonetheless available to the person applying the pesticide, unless the Agency has determined that the pesticide may only be applied under the direct supervision of a certified applicator who is physically present.

(F) Other pertinent information which the Administrator determines to be necessary for the protection of man and the environment.

(j) Statement of Use Classification. By October 22, 1976, all pesticide products must bear on their labels a statement of use classification as described in paragraphs (j)(1) and (2) of this section. Any pesticide product for which some uses are classified for general use and others for restricted use shall be separately labeled according to the labeling standards set forth in this subsection, and shall be marketed as separate products with different registration numbers, one bearing directions only for general use(s) and the other bearing directions for restricted use(s) except that, if a product has both restricted use(s) and general use(s), both of these uses may appear on a product labeled for restricted use. Such products shall be subject to the provisions of §162.10(j)(2).

(1) General Use Classification. Pesticide products bearing directions for use(s) classified general shall be labeled with the exact words "General Classification" immediately below the heading "Directions for Use," and reference to the general classification that suggests or implies that the general utility of the pesticide extends beyond those purposes and uses contained in the Directions for Use will be considered a false or misleading statement under the statutory definitions of misbranding.

(2) Restricted Use Classification. Pesticide products bearing direction for use(s) classified restricted shall bear statements of restricted use classification on the front panel as described below:

(i) Front panel statement of restricted use classification. (A) At the top of the front panel of the label, set in type of the same minimum sizes as required for human hazard signal words (see table in §162.10(h)(1)(iv)), and appearing with sufficient prominence relative to other text and graphic material on the front panel to make it unlikely to be overlooked under customary conditions of purchase and use, the statement "Restricted Use Pesticide" shall appear.

(B) Directly below this statement on the front panel, a summary statement of the terms of restriction imposed as a precondition to registration shall appear. If use is restricted to certified applicators, the following statement is required: "For retail sale to and use only by Certified Applicators or persons under their direct supervision and only for those uses covered by the Certified Applicator's certification." If, however, other regulatory restrictions are imposed, the Administrator will define the appropriate wording for the terms of restriction by regulation.

(k) Advertising. [Reserved]

[40 CF 28268, July 3, 1975; 40 FR 32329, August 1, 1975; 40 FR 38571, August 21, 1975, as amended at 43 FR 5786, February 9, 1978; amended at 53 FR 15952, May 4, 1988.

PHYSICAL-CHEMICAL HAZARDS

Criteria	Required Label Statement
I. Pressurized Containers	
A. Flashpoint at or below 20°F; or if there is a flashback at any valve opening.	Extremely flammable. Contents under pressure. Keep away from fire, sparks, and heated surfaces. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
B. Flashpoint above 20°F and not over 80°F; or if the flame extension is more than 18 inches long at a distance of 6 inches from the valve opening.	Flammable. Contents under pressure. Keep away from heat, sparks, and flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
C. ALL OTHER PRESSURIZED CONTAINERS	Contents under pressure. Do not use or store near heat or open flame. Do not puncture or incinerate container. Exposure to temperatures above 130°F may cause bursting.
II. Non-Pressurized Containers	
A. Flashpoint at or below 20°F.	Extremely flammable. Keep away from fire, sparks, and heated surfaces.
B. Flashpoint above 20°F and not over 80°F.	Flammable. keep away from heat and open flame.
C. Flashpoint over 80°F and not over 150°F.	Do not use or store near heat and open flame.
D. Flashpoint above 150°F.	None required.

STOR-1

STORAGE INSTRUCTIONS FOR PESTICIDES

Heading:

All products are required to bear specific label instructions about storage and disposal. Storage and disposal instructions must be grouped together in the directions for use portion of the label under the heading STORAGE AND DISPOSAL. Products intended solely for domestic use need not include the heading "STORAGE AND DISPOSAL."

Storage Instructions:

All product labels are required to have appropriate storage instructions. Specific storage instructions are not prescribed. Each registrant must develop his own storage instructions, considering, when applicable, the following factors:

1. Conditions of storage that might alter the composition or usefulness of the pesticide. Examples could be temperature extremes, excessive moisture or humidity, heat, sunlight, friction, or contaminating substances or media.
2. Physical requirements of storage which might adversely affect the container of the product and its ability to continue to function properly. Requirements might include positioning of the container in storage, storage or damage due to stacking, penetration of moisture, and ability to withstand shock or friction.
3. Specifications for handling the pesticide container, including movement of container within the storage area, proper opening and closing procedures (particularly for opened containers), and measures to minimize exposure while opening or closing container.
4. Instructions on what to do if the container is damaged in any way, or if the pesticide is leaking or has been spilled, and precautions to minimize exposure if damage occurs.
5. General precautions concerning locked storage, storage in original container only, and separation of pesticides during storage to prevent cross-contamination of other pesticides, fertilizer, food, and feed.
6. General storage instructions for household products should emphasize storage in original container and placement in locked storage areas.

PEST/DIS-1

PESTICIDE DISPOSAL INSTRUCTIONS

The label of all products, except those intended solely for domestic use, must bear explicit instructions about pesticide disposal. The statements listed below contain the exact wording that must appear on the label of these products:

1. The labels of all products, except domestic use, must contain the statement, "Do not contaminate water, food, or feed by storage or disposal."

2. Except those products intended solely for domestic use, the labels of all products that contain active ingredients that are Acute Hazardous Wastes or are assigned to Toxicity Category I on the basis of oral or dermal toxicity, or Toxicity Category I or II on the basis of acute inhalation toxicity must bear the following pesticide disposal statement:

> "Pesticide wastes are acutely hazardous. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

3. The labels of all products, except those intended for domestic use, containing active or inert ingredients that are Toxic Hazardous Wastes or meet any of the criteria in 40 CFR 261, Subpart C for a hazardous waste must bear the following pesticide disposal statement:

> "Pesticide wastes are toxic. Improper disposal of excess pesticide, spray mixture, or rinsate is a violation of Federal Law. If these wastes cannot be disposed of by use according to label instructions, contact your State Pesticide or Environmental Control Agency, or the Hazardous Waste representative at the nearest EPA Regional Office for guidance."

4. Labels for all other products, except those intended for domestic use, must bear the following pesticide disposal statement:

> "Wastes resulting from the use of this product may be disposed of on site or at an approved waste disposal facility."

5. Products intended for domestic use only must bear the following disposal statement: "Securely wrap original container in several layers of newspaper and discard in trash."

CONT/DIS-1

CONTAINER DISPOSAL INSTRUCTIONS

The label of each product must bear container disposal instructions appropriate to the type of container.

1. Domestic use products must bear one of the following container disposal statements:

Container Type	Statement
Non-aerosol products (bottles, cans, jars)	Do not reuse container (bottle, can, jar). Rinse thoroughly before discarding in trash.
Non-aerosol products (bags)	Do not reuse bag. Discard bag in trash.
Aerosol products	Replace cap and discard containers in trash. Do not incinerate or puncture.

2. All other products must bear container disposal instructions, based on container type, listed below:

Container Type	Statement
Metal containers (non-aerosol)	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or by other procedures approved by state and local authorities.
Plastic containers	Triple rinse (or equivalent). Then offer for recycling or reconditioning, or puncture and dispose of in a sanitary landfill, or incineration, or, if allowed by state and local authorities, by burning. If burned, stay out of smoke.
Glass containers	Triple rinse (or equivalent). Then dispose of in a sanitary landfill or by other approved state and local procedures.
Fiber drums with liners	Completely empty liner by shaking and tapping sides and bottom to loosen clinging particles. Empty residue into application equipment. Then dispose of liner in a sanitary landfill or by incineration if allowed by state and local authorities. If drum is contaminated and cannot be reused[1], dispose of in the same manner.
Paper and plastic bags	Completely empty bag into application equipment. Then dispose of empty bag in a sanitary landfill or by incineration, or, if allowed by State and local authorities, by burning. If burned, stay out of smoke.
Compressed gas cylinders	Return empty cylinder for reuse (or similar wording).

[1] Manufacturer may replace this phrase with one indicating whether and how fiber drum may be reused.

III. BIBLIOGRAPHY APPENDICES

Guide to Use of This Bibliography

1. CONTENT OF BIBLIOGRAPHY. This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Standard. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, will be included.

2. UNITS OF ENTRY. The unit of entry in this bibliography is called a "study." In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review, and can be described with a conventional bibliographic citation. The Agency has attempted also to unite basic documents and commentaries upon them, treating them as a single study.

3. IDENTIFICATION OF ENTRIES. The entries in this bibliography are sorted numerically by "Master Record Identifier," or MRID, number. This number is unique to the citation, and should be used at any time specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies; see paragraph 4(d)(4) below for a further explanation. In a few cases, entries added to the bibliography late in the review may be preceded by a nine-character temporary identifier. These entries are listed after all MRID entries. This temporary identifier number is also to be used whenever specific reference is needed.

4. FORM OF ENTRY. In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standards of the American National Standards Institute (ANSI), expanded to provide for certain special needs.

   a. Author. Whenever the Agency could confidently identify one, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as author. As a last resort, the Agency has shown the first submitter as author.

b. Document Date. When the date appears as four digits with no question marks, the Agency took it directly from the document. When a four-digit date is followed by a question mark, the bibliographer deduced the date from evidence in the document. When the date appears as (19??), the Agency was unable to determine or estimate the date of the document.

c. Title. In some cases, it has been necessary for Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.

d. Trailing Parentheses. For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:

   (1) Submission Date. The date of the earliest known submission appears immediately following the word "received."

   (2) Administrative Number. The next element, immediately following the word "under," is the registration number, experimental use permit number, petition number or other administrative number associated with the earliest known submission.

   (3) Submitter. The third element is the submitter, following the phrase "submitted by." When authorship is defaulted to the submitter, this element is omitted.

   (4) Volume Identification (Accession Numbers). The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," standing for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume. For example, within accession number 123456, the first study would be 123456-A; the second, 123456-B; the 26th, 123456-Z; and the 27th, 123456-AA.

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00004443	Thornburg, W. (1973) MCPA Residues in Peas: A Summary of Residue Data. (Unpublished study received on unknown date under 9F0761; prepared by Del Monte Corp., submitted by Dow Chemical U.S.A., Midland, Mich.; CDL:092000-I)
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00004491	Herman, J.L.; Bjerke, E.L.; Getzendaner, M.E. (1970) Residue of 2-Methyl-4-chlorophenoxyacetic acid and 2-Methyl-4-chlorophenol in Milk and Cream from Cows Fed MCPA. (Unpublished study received Jan 11, 1971 under 9F0761; prepared by Dow Chemical Co., submitted by National Agricultural Chemicals Association, Industry Task Force on Phenoxy Herbicide Tolerances, Washington, D.C.; CDL:091313-I)
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00005575	Montgomery, M.L. (1970) MCPA Residue in Wheat: Oregon State University Report. Includes methods dated Jun 17, 1970 and Apr 1, 1970. (Unpublished study including summary report and letters dated Apr 2, 1970 from M.L. Montgomery to Don T. Lillie and J.A. Ignatoski, received Jan 22, 1971 under 9F0761; prepared by Oregon State Univ., Dept. of Agricultural Chemistry, submitted by National Agricultural Chemicals Association, Industry Task Force on Phenoxy Herbicide Tolerances, Washington, D.C.; CDL:091308-I)
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IV. FORMS APPENDICES

Form Approved. OMB No. 2070-0057. Approval expires 11-30-89.

FIFRA SECTION 3(C)(2)(B) SUMMARY SHEET	EPA REGISTRATION NO.
PRODUCT NAME	
APPLICANT'S NAME	DATE GUIDANCE DOCUMENT ISSUED

With respect to the requirement to submit "generic" data imposed by the FIFRA section 3(C)(2)(B) notice contained in the referenced Guidance Document, I am responding in the following manner:

☐ 1. I will submit data in a timely manner to satisfy the following requirements. If the test procedures I will use deviate from (or are not specified in) the Registration Guidelines or the Protocols contained in the Reports of Expert Groups to the Chemicals Group, OECD Chemicals Testing Programme, I enclose the protocols that I will use:

☐ 2. I have entered into an agreement with one or more other registrants under FIFRA section 3(C)(2)(B)(ii) to satisfy the following data requirements. The tests, and any required protocols, will be submitted to EPA by:

NAME OF OTHER REGISTRANT

☐ 3. I enclose a completed "Certification of Attempt to Enter Into an Agreement with Other Registrants for Development of Data" with respect to the following data requirements:

☐ 4. I request that you amend my registration by deleting the following uses (this option is not available to applicants for new products):

☐ 5. I request voluntary cancellation of the registration of this product. (This option is not available to applicants for new products.)

REGISTRANT'S AUTHORIZED REPRESENTATIVE	SIGNATURE	DATE

EPA Form 8580-1 (10-82)

OMB Approval No. 2070-0057
Expiration Date 11/30/89

GENERIC DATA EXEMPTION STATEMENT

EPA Product Registration Number:_______________________

Registrant's Name and Address: ____

____

As an authorized representative of the registrant of the product identified above, I certify that:

(1) I have read and am familiar with the terms of the Notice from EPA dated _____________ concerning a requirement for submission of "generic" data on the active ingredient _______________________ named under FIFRA Section 3(c)(2)(B).

(2) My firm requests that EPA not suspend the registration of our product, despite our lack of intent to submit the generic data in question, on the grounds that the product contains the active ingredient solely as the result of the incorporation into the product of another product which contains that active ingredient, which is registered under FIFRA Section 3, and which is purchased by us from another producer.

(3) An accurate Confidental Statement of Formula (CSF) for the above-identified product is attached to this statement. That formula statement indicates, by company name, registration number, and product name, the source of the subject active ingredient in my firm's product, or

The CSF dated___________________ on file with EPA is complete, current and accurate and contains the information requested on the current CSF Form 8570-4. The registered source(s) of the above named active ingredient in my product(s) is/are _______________ and their registration number(s) is/are ____________________.

My firm will apply for an amendment to the registration prior to changing the source of the active ingredient in our product.

(4) I understand, and agree on behalf of my firm, that if at any time any portion of this Statement is no longer true, or if my firm fails to comply with the undertakings made in this Statement, my firm's product's registration may be suspended under FIFRA Section 3(c)(2)(B).

(5) I further understand that if my firm is granted a generic data exemption for the product, my firm relies on the efforts of other persons to provide the Agency with the required generic data. If the registrant(s) who have committed to generate and submit the required data fail to take appropriate steps to meet requirements or are no longer in compliance with this Notice's data requirements, the Agency will consider that both they and my firm are not in compliance and will normally initiate proceedings to suspend the registrations of my firm's product(s) and their product(s), unless my firm commits to submit and submits the required data in the specified time frame. I understand that, in such cases, the Agency generally will not grant a time extension for submitting the data.

Registrant's authorized representative:___________________________________
(Signature

Dated: ____________________ ___________________________________
(Typed)

EPA Form 8570-27

EPA

US Environmental Protection Agency
Washington, DC 20460

Product Specific Data Report

Registration Standard for:

EPA Registration Number

Form Approved
OMB #2070-0057
Expires 11-30-89

Registration Guideline No.	Name of Test	Testing not required for my product listed above *(Check below)*	I am complying with Data Requirements by -		(For EPA Use Only) Accession numbers assigned
			Citing MR ID No.	Submitting Data *(Attached)* *(Check below)*	
Sec. 158.120 Product Chemistry					
61-1	Identity of ingredients				
61-2	Statement of composition				
61-3	Discussion of formation of ingredients				
62-1	Preliminary analysis				
62-2	Certification of limits				
62-3	Analytical methods for enforcement limits				
63-2	Color				
63-3	Physical state				
63-4	Odor				
63-5	Melting point				
63-6	Boiling point				
63-7	Density, bulk-density, or specific gravity				
63-8	Solubility				
63-9	Vapor pressure				
63-10	Dissociation constant				
63-11	Octanol/water partition coefficient				
63-12	pH				
63-13	Stability				
63-14	Oxidizing/reducing reaction				
63-15	Flammability				
63-16	Explodability				
63-17	Storage stability				
63-18	Viscosity				
63-19	Miscibility				
63-20	Corrosion Characteristics				
63-21	Dielectric breakdown voltage				
Sec. 158.135 Toxicology					
81-1	Acute oral toxicity, rat				
81-2	Acute dermal toxicity, rabbit				
81-3	Acute inhalation toxicity, rat				
81-4	Primary eye irritation, rabbit				
81-5	Primary dermal irritation				
81-6	Dermal sensitization				

Certification

I certify that the statements I have made on this form and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Typed Name and Title	Signature	Date

EPA Form 8580-4 (Rev. 5-88) Previous edition is obsolete.

Form Approved. OMB No. 2070-0057. Expires 11-30-89.

CERTIFICATION OF ATTEMPT TO ENTER INTO AN AGREEMENT WITH OTHER REGISTRANTS FOR DEVELOPMENT OF DATA

(To qualify, certify ALL four items)

1. I am duly authorized to represent the following firm(s) who are subject to the requirements of a Notice under FIFRA Section 3(c)(2)(B) contained in a Guidance Document to submit data concerning the active ingredient:

GUIDANCE DOCUMENT DATE

ACTIVE INGREDIENT

NAME OF FIRM	EPA COMPANY NUMBER

(This firm or group of firms is referred to below as "my firm".)

2. My firm is willing to develop and submit the data as required by that Notice, if necessary. However, my firm would prefer to enter into an agreement with one or more other registrants to develop jointly, or to share in the cost of developing, the following required items of data:

3. My firm has offered in writing to enter into such an agreement. Copies of the offers are attached. That offer was irrevocable and included an offer to be bound by an arbitration decision under FIFRA Section 3(c)(2)(B)(iii) if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

NAME OF FIRM	DATE OF OFFER

However, none of those firm(s) accepted my offer.

4. My firm requests that EPA not suspend the registration(s) of my firm's product(s), if any of the firms named in paragraph (3) above have agreed to submit the data listed in paragraph (2) above in accordance with the Notice. I understand EPA will promptly inform me whether my firm must submit data to avoid suspension of its registration(s) under FIFRA Section 3(c)(2)(B). (This statement does not apply to applicants for new products.) I give EPA permission to disclose this statement upon request.

TYPED NAME	SIGNATURE	DATE

EPA Form 8580-6 (10-82)